ISRCTN49639731 https://doi.org/10.1186/ISRCTN49639731

Routine testing for Group B Streptococcus in pregnancy (GBS3 trial)

Submission date	Recruitment status	[X] Prospectively registered
19/08/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
23/08/2019	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/08/2025	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Group B Streptococcus (GBS) is a bacterium present in the vagina of approximately 1 in 4 pregnant women. Giving women antibiotics in labour reduces the risk of their babies developing GBS infection. Current UK practice is to offer antibiotics when the baby is at higher risk of developing the infection based on maternal risk factors. This “risk factor” screening is imperfect: some babies born to mothers without risk factors still develop an infection and many women with risk factors do not carry GBS but receive antibiotics unnecessarily. A better solution is “routine testing” of every pregnant woman, and offering antibiotics in labour to those who are carrying GBS.

Who can participate?
All pregnant women giving birth at 24 or more weeks gestation within their maternity unit’s recruitment period can be included in the data collection. Up to 50 women over 16 years old and 30 healthcare professionals at some sites will be asked to take part in the qualitative sub-study.

What does the study involve?
We will work with up to 80 hospitals/ boards or trusts. Hospitals will be randomly allocated to the “risk factor” or the “routine testing” approach. Hospitals allocated to the “routine testing” approach will be further randomly divided into testing women using a swab taken from the vagina and rectum either a) at approximately 35-37 weeks of pregnancy, or b) in labour, using a rapid test machine. Women with a positive test result will be offered antibiotics in labour. All mothers in preterm labour or who had a previous baby with a GBS infection will be offered antibiotics as per current guidance. We will compare the number of babies who develop serious infections born in all “routine testing” hospitals and birth centres with those using the “risk factor” approach. As infections are relatively rare, we will need to collect information on 320,000 women to be able to see a difference between the two main approaches. We will use routinely collected data from national systems to avoid burdening busy clinical staff. We will also interview women and healthcare professionals about the acceptability of the testing approaches. Finally, we will compare the overall costs of each strategy and work out which represents the best value for money for the NHS.

What are the possible benefits and risks of participating?
The trial does not benefit women directly but the information we get from this trial may help us to treat pregnant women with Group B Streptococcus in future

Where is the study run from?
The trial is managed by the Nottingham Clinical Trials Unit which is part of the University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
April 2019 to August 2025

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
gbs3@nottingham.ac.uk

Study website
http://www.GBS3Trial.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Prof Jane Daniels

ORCID ID
https://orcid.org/0000-0003-3324-6771

Contact details
Nottingham Clinical Trials Unit
University of Nottingham
Building 42 Room BO4
University Park
Nottingham
United Kingdom
NG7 2RD
+44115 82 31619
jane.daniels@nottingham.ac.uk

Type(s)
Scientific

Contact name
Dr Kate Walker

ORCID ID
https://orcid.org/0000-0001-5794-7324

Contact details
Nottingham Clinical Trials Unit
Building 42 Room B03
University Park
University of Nottingham
Nottingham
United Kingdom
NG7 2RD
+441158231581
kate.walker@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263682

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42782, IRAS 263682

Study information

Scientific Title
The clinical and cost-effectiveness of testing for Group B Streptococcus: a cluster randomised trial with economic and acceptability evaluations (GBS3)

Acronym
GBS3

Study objectives
Does routine testing of women for GBS colonisation either in late pregnancy or during labour reduce the occurrence of early-onset neonatal sepsis, compared to the current risk factor based strategy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/10/2019, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +442071048036; derby.rec@hra.nhs.uk), ref: 19/EM/0253, 19/CAG/0139

Study design
Randomized qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please email GBS3@nottingham.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Group B streptococcus infection in pregnancy

Interventions
Current interventions as of 27/03/2024:
We will work with up to 80 maternity units in England and Wales. Maternity units will be randomly allocated to the “risk factor” or the “routine testing” approach. Maternity units allocated to the “routine testing” approach will be further randomly divided into testing women using a swab taken from the vagina and rectum either a) at approximately 35-37 weeks of pregnancy, using a lab-based test or b) in labour, using a rapid test machine. So, all eligible women at the same hospital will receive the same treatment.

Information for the trial will be displayed on posters in the maternity units, on patient information sheets (Available upon request), and on the website. Women in risk-factors sites will also be provided with the leaflet ‘Group B Streptococcus in pregnancy and newborn babies’ (produced by the Royal College of Obstetricians & Gynaecologists and the Group B Strep Support charity) at approximately their 28-week antenatal appointment. Women in either of the two testing arms will be provided with an adapted version of the leaflet at approximately their 28-week antenatal appointment which also contains information on the GBS3 trial and the vaginal-rectal swab. Women will not be routinely given a trial-specific patient information sheet, and written informed consent will not be received. If the maternity unit has been randomised to routine testing the swab process will be explained to the women, and verbal consent will be sought for taking the swab.

Bedside Test at the start of labour (Known as Intrapartum Rapid Testing): A swab will be taken from both the vagina and rectum (back passage) whilst the woman is in labour. This is taken by a healthcare professional. The procedure will not hurt but it may be slightly uncomfortable. The swab will be put immediately into a machine by a member of the woman’s care team and the results will be available within one hour. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics immediately. Women planning to give birth at home or in a midwife-only-led unit (which is not unable to offer antibiotics during labour) will be offered the option of a rapid test antenatally in the hospital in or after the 35th week of pregnancy.

Lab-Based Test (Known as Antenatal Enriched Culture Medium Test): A swab from both the vagina and rectum (back passage) will be taken approximately 3-5 weeks before the expected due date. This can be taken by a healthcare professional or by the woman herself. The procedure will not hurt but it may be slightly uncomfortable. The swab will be sent to the woman's hospital laboratory for testing and women will be informed if the test is positive. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics during labour.

Usual care (Known as Risk Factor Based Strategy): Sites will follow their current risk factor-based screening and treatment approach. The RCOG Greentop Guideline No. 36 states women with the following risk factors for EOGBS infection should be offered IAP:
•Having a previous baby with a GBS infection
•Discovery of maternal GBS carriage incidentally during pregnancy
•Preterm labour
•Suspected maternal intrapartum infection, including suspected chorioamnionitis
•Intrapartum pyrexia (raised temperature)
•Women who are known to be colonised with GBS in a previous pregnancy should be offered the option of IAP or ECM testing in late pregnancy with the offer of IAP if GBS is detected. The risk of colonisation in subsequent pregnancies described in the RCOG guidelines should be discussed with the woman.

As infections are relatively rare, we will need to collect information on 320,000 women to be able to see a difference between the two main approaches.

For the main study, routine data about the woman and her baby will be obtained from different routine data sources such as NHS England, Public Health England, National Neonatal Research Database, Paediatric Intensive Care Audit Network, Badgernet and other devolved nation equivalents. Data will also be collected from medical notes as some outcomes cannot be obtained from Routine Data Sources. This information will have all patient identifiers removed after the information has been linked by a researcher.

If women do not want their data to be used/don't want their baby's data to be used they can ensure this by using the national data opt-out (or equivalent in Scotland and Wales). This is a service which allows you to opt out of all your health information being used for all future research and planning, (not just for this trial).
In all of the maternity units, posters will be displayed which will give details of how to opt out. This information will also be present on the website, and on the trial patient information sheets, which will be available upon request.

We will also interview some women and healthcare professionals about the acceptability of the testing approaches, via the qualitative sub-study. In 4 maternity units, randomised to "routine testing", women and healthcare professionals will be asked to take part in the qualitative sub-study. They may be approached by a member of their local usual care team (including the local Research Team) or may be able to refer themselves. These women and staff members will be provided with an information sheet and written informed consent will be received before the interviews are undertaken.

We will also collect individual-level detailed data for at least 100 consecutive women per site to inform the economic evaluation of the trial and for monitoring purposes. Neonatal adjudication will be conducted on a sample of clinically suspected sepsis cases and any cases of maternal intrapartum anaphylaxis will be reported by sites quarterly.

Finally, we will compare the overall costs of each strategy and work out which represents the best value for money for the NHS, via the economic evaluation sub-study.

_____

Previous interventions as of 24/08/2021:

We will work with 80 maternity units in England, Scotland and Wales. Maternity units will be randomly allocated to the “risk factor” or the “routine testing” approach. Maternity units allocated to the “routine testing” approach will be further randomly divided into testing women using a swab taken from the vagina and rectum either a) at approximately 35-37 weeks of pregnancy, using a lab based test or b) in labour, using a rapid test machine. So, all eligible women at the same hospital will receive the same treatment.

Information for the trial will be displayed on posters in the maternity units, on patient information sheets (Available upon request), and the website. Women in risk-factors sites will also be provided with the leaflet ‘Group B Streptococcus in pregnancy and newborn babies’ (produced by the Royal College of Obstetricians & Gynaecologists and the Group B Strep Support charity) at approximately their 28 week antenatal appointment. Women in either of the two testing arms will be provided with an adapted version of the leaflet at approximately their 28 week antenatal appointment which also contains information on the GBS3 trial and the vaginal-rectal swab. Women will not be routinely given a trial specific patient information sheet, and written informed consent will not be received. If the maternity unit has been randomised to routine testing the swab process will be explained to the women, and verbal consent will be sought for taking the swab.

Bedside Test at start of labour (Known as Intrapartum Rapid Testing): A swab will be taken from both the vagina and rectum (back passage) whilst the woman is in labour. This is taken by a healthcare professional. The procedure will not hurt but it may be slightly uncomfortable. The swab will be put immediately into a machine by a member of the woman’s care team and the results will be available within one hour. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics immediately. Women planning to give birth at home or in a midwife only led unit (which is not unable to offer antibiotics during labour) will be offered the option of a rapid test antenatally in hospital in or after the 35th week of pregnancy.

Lab Based Test (Known as Antenatal Enriched Culture Medium Test): A swab from both the vagina and rectum (back passage) will be taken at approximately 3-5 weeks before the expected due date. This can be taken by a healthcare professional or by the woman herself. The procedure will not hurt but it may be slightly uncomfortable. The swab will be sent to the woman’s hospital laboratory for testing and women will be informed if the test is positive. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics during labour.

Usual care (Known as Risk Factor Based Strategy): Sites will follow their current risk factor based screening and treatment approach. The RCOG Greentop Guideline No. 36 states women with the following risk factors for EOGBS infection should be offered IAP:
•Having a previous baby with GBS infection
•Discovery of maternal GBS carriage incidentally during pregnancy
•Preterm labour
•Suspected maternal intrapartum infection, including suspected chorioamnionitis
•Intrapartum pyrexia (raised temperature)
•Women who are known to be colonised with GBS in a previous pregnancy should be offered the options of IAP or ECM testing in late pregnancy with the offer of IAP if GBS is detected. The risk

of colonisation in subsequent pregnancies described in the RCOG guidelines should be discussed with the woman.

As infections are relatively rare, we will need to collect information on 320,000 women to be able to see a difference between the two main approaches.

For the main study, routine data about the woman and her baby will be obtained from different routine data sources such as NHS Digital, Public Health England, National Neonatal Research Database, Paediatric Intensive Care Audit Network, Badgernet and other devolved nation equivalents. Data will also be collected from medical notes as some outcomes cannot be obtained from Routine Data Sources. This information will have all patient identifiers removed after information has been linked by researcher.

If women do not want their data to be used/don't want their baby's data to be used they can ensure this by using the national data opt-out (or equivalent in Scotland and Wales). This is a service which allows you to opt out of all your health information being used for all future research and planning, (not just for this trial).
In all of the maternity units, posters will be displayed which will give details of how to opt-out. This information will also be present on the website, and on the trial patient information sheets, which will be available upon request.

We will also interview some women and healthcare professionals about the acceptability of the testing approaches, via the qualitative sub-study. In 4 maternity units, randomised to "routine testing", women and healthcare professionals will be asked to take part in the qualitative sub-study. They may be approached by a member of their local usual care team (including local Research Team), or may be able to refer themselves. These women and staff members will be provided with an information sheet and written informed consent will be received before the interviews are undertaken.

We will also collect individual-level detailed data for 100 consecutive women at each of the 80 sites to inform the economic evaluation of the trial and for monitoring purposes. Neonatal adjudication will be conducted on a sample of clinically suspected sepsis cases and any cases of maternal intrapartum anaphylaxis will be reported by sites on a quarterly basis.

Finally, we will compare the overall costs of each strategy and work out which represents the best value for money for the NHS, via the economic evaluation sub-study.

———

Previous interventions as of 27/10/2020:

We will work with 80 maternity units in England, Scotland and Wales. Maternity units will be randomly allocated to the "risk factor" or the "routine testing" approach. Maternity units allocated to the "routine testing" approach will be further randomly divided into testing women using a swab taken from the vagina and rectum either a) at approximately 35-37 weeks of pregnancy, using a lab based test or b) in labour, using a rapid test machine. So, all eligible women at the same hospital will receive the same treatment.

Information for the trial will be displayed on posters in the maternity units, on patient information sheets (Available upon request), and the website. Women in risk-factors sites will also be provided with the leaflet 'Group B Streptococcus in pregnancy and newborn babies' (produced by the Royal College of Obstetricians & Gynaecologists and the Group B Strep

Support charity) at approximately their 28 week antenatal appointment. Women in either of the two testing arms will be provided with an adapted version of the leaflet at approximately their 28 week antenatal appointment which also contains information on the GBS3 trial and the vaginal-rectal swab. Women will not be routinely given a trial specific patient information sheet, and written informed consent will not be received. If the maternity unit has been randomised to routine testing the swab process will be explained to the women, and verbal consent will be sought for taking the swab.

Bedside Test at start of labour (Intrapartum Rapid Testing)A swab will be taken from both the vagina and rectum (back passage) whilst the woman is in labour. This is taken by a healthcare professional. The procedure will not hurt but it may be slightly uncomfortable. The swab will be put immediately into a machine by a member of the woman's care team and the results will be available within one hour. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics immediately. Women planning to give birth at home or in a midwife only led unit will be offered the option of a rapid test antenatally in hospital in or after the 35th week of pregnancy.

Antenatal Enriched Culture Medium Test (Lab Based Test) : A swab from both the vagina and rectum (back passage) will be taken at approximately 3-5 weeks before the expected due date. This can be taken by a healthcare professional or by the woman herself. The procedure will not hurt but it may be slightly uncomfortable. The swab will be sent to the woman's hospital laboratory for testing and women will be informed if the test is positive. If the result is positive for Group B Streptococcus, the woman will be offered antibiotics during labour.

Usual care: Sites will follow their current risk factor based screening and treatment approach. The RCOG Greentop Guideline No. 36 states women with the following risk factors for EOGBS infection should be offered IAP:
•Having a previous baby with GBS infection
•Discovery of maternal GBS carriage incidentally during pregnancy
•Preterm labour
•Suspected maternal intrapartum infection, including suspected chorioamnionitis
•Intrapartum pyrexia (raised temperature)
•Women who are known to be colonised with GBS in a previous pregnancy should be offered the options of IAP or ECM testing in late pregnancy with the offer of IAP if GBS is detected. The risk of colonisation in subsequent pregnancies described in the RCOG guidelines should be discussed with the woman.

As infections are relatively rare, we will need to collect information on 320,000 women to be able to see a difference between the two main approaches.

For the main study, routine data about the woman and her baby will be obtained from different routine data sources such as NHS Digital, Public Health England, National Neonatal Research Database, Paediatric Intensive Care Audit Network and other devolved nation equivalents. Data will also be collected from medical notes as some outcomes cannot be obtained from Routine Data Sources. This information will have all patient identifiers removed after information has been linked by researcher.

If women do not want their data to be used/don't want their baby's data to be used they can ensure this by using the national data opt-out (or equivalent in Scotland and Wales). This is a service that allows you to opt out of all your health information being used for all future research and planning, (not just for this trial)
In all of the maternity units, posters will be displayed which will give details of how to opt-out.

This information will also be present on the website, and on the trial patient information sheets, which will be available upon request.

We will also interview some women and healthcare professionals about the acceptability of the testing approaches, via the qualitative sub-study. In 4 maternity units, randomised to “routine testing”, women and healthcare professionals will be asked to take part in the qualitative sub-study. They may be approached by a member of their local usual care team (including local Research Team), or may be able to refer themselves. These women and staff members will be provided with an information sheet and written informed consent will be received before the interviews are undertaken.

We will also collect individual-level detailed data for 100 consecutive women at each of the 80 sites to inform the economic evaluation of the trial and for monitoring purposes. Neonatal adjudication will be conducted on a sample of clinically suspected sepsis cases and any cases of maternal intrapartum anaphylaxis will be reported by sites on a quarterly basis.

Finally, we will compare the overall costs of each strategy and work out which represents the best value for money for the NHS, via the economic evaluation sub-study

_____

Previous interventions:

We will work with 80 maternity units. Maternity units will be randomly allocated to the “risk factor” or the “routine testing” approach. Maternity units allocated to the “routine testing” approach will be further randomly divided into testing women using a swab taken from the vagina and rectum either a) at 35-37 weeks of pregnancy, using a lab based test or b) in labour, using a rapid test kit. So all eligible women at the same hospital will receive the same treatment.

Information for the trial will be displayed on posters in the maternity units, and on patient information sheets (Available upon request), and the website. Women will not be routinely given a patient information sheet, and written informed consent will not be received. If the maternity unit has been randomised to routine testing the swab process will be explained to the women, and verbal consent will be sought for taking the swab.

Bedside Test: A swab will be taken from both the vagina and rectum (back passage) whilst the women is in labour. This can be taken by a healthcare professional or the women herself. The procedure will not hurt but it may be slightly uncomfortable. The swab will be put immediately into a machine by a member of the women’s care team and the results will be available within one hour. If the result is positive for Group B Streptococcus, the women will be offered antibiotics during labour.

Lab Based Test: A swab from both the vagina and rectum (back passage) when the women is 35-37 weeks pregnant will be taken. This can be taken by a healthcare professional or by the women herself. The procedure will not hurt but it may be slightly uncomfortable. The swab will be sent to the women’s hospital laboratory for testing and results will be sent to the women within 3 days. If the result is positive for Group B Streptococcus, the women will be offered antibiotics during labour.
Usual care: Sites will follow the current risk factor based screening and treatment approach. The RCOG Greentop Guideline No. 36 states women with the following risk factors for EOGBS infection should be offered IAP:
•Having a previous baby with GBS disease

•Discovery of maternal GBS carriage incidentally during pregnancy
•Preterm birth
•Suspected maternal intrapartum infection, including suspected chorioamnionitis
•Intrapartum raised temperature
•Women colonised in a previous pregnancy should have intrapartum prophylaxis discussed

As infections are relatively rare, we will need to collect information on 320,000 women to be able to see a difference between the two main approaches.

For the main study, routine data about the woman and her baby will be obtained from different NHS databases through NHS digital. This information will have all patient identifiers removed after information has been linked.

If women do not want to take part in the study/don't want their baby to take part in the study they can do so by the national data opt-out. In all of the maternity units, posters will be displayed explaining the trial, and what it will entail including details of how to opt-out. This information will also be present on the website, and on the patient information sheets, which will be available upon request.

We will also interview some women and healthcare professionals about the acceptability of the testing approaches, via the qualitative sub-study. In 4 maternity units women and healthcare professionals will be asked to take part in the qualitative sub-study. They will be approached by a member of their local usual care team (including local Research Team if local operating policies permit this), or may be able to refer themselves. These women and staff members will be provided with an information sheet and written informed consent will be received before the interviews are undertaken.

We will collect individual-level detailed data for 100 women at each of the 80 sites to inform the economic evaluation of the trial and for monitoring purposes.

Finally, we will compare the overall costs of each strategy and work out which represents the best value for money for the NHS, via the economic evaluation sub-study.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 27/03/2024:
All-cause early neonatal sepsis defined as starting at < 7 days of birth. Cases will be identified from national data sources, a sample of which will be reviewed by a blinded adjudication panel. Early neonatal sepsis will be defined as:
1. A positive culture of a pathogenic bacteria from blood or cerebrospinal fluid taken at <7 days of birth, or
2. Death <7 days if infection or sepsis was recorded on the death certificate, or
3. Negative/ unknown culture status with ≥3 agreed clinical signs or symptoms (see list below), for which intravenous antibiotics are given for ≥5 days, starting within 7 days of birth.

Previous primary outcome measure as of 30/03/2022:
All-cause early neonatal sepsis, defined as:
1. Either culture-positive (blood or cerebrospinal fluid) taken at <7 days of birth, or

2. Negative/ unknown culture status with ≥3 agreed clinical signs or symptoms, for which intravenous antibiotics are given for ≥5 days, starting within 7 days of birth.

_____

Previous primary outcome measure as of 27/10/2020:
Early neonatal sepsis, defined as:
1. Either culture-positive (blood or cerebrospinal fluid) taken at <7 days of birth or
2. Negative/ unknown culture status with ≥3 agreed clinical signs or symptoms, for which intravenous antibiotics are given for ≥5 days, starting within 7 days of birth.

_____

Previous primary outcome measure:

All-cause early neonatal sepsis: either culture-positive (blood or cerebrospinal fluid) or negative/ unknown culture status with ≥ 3 agreed clinical signs or symptoms, for which antibiotics are given for ≥ 5 days, within 7 days of birth

Secondary outcome measures

Current secondary outcome measures as of 27/03/2024:
1. Neonatal
1.1 Birth Weight
1.2. Perinatal mortality (a stillbirth or early neonatal death, <7 days)
1.3. Extended perinatal mortality (a stillbirth or neonatal death, <28 days)
1.4. Baby death before discharge
1.5. 5-minute Apgar
1.6. Fetal acidaemia, defined as cord arterial pH < 7.05
1.7. Gestational age at birth
1.8. Admission for neonatal specialist care (length of stay, level of care)
1.9. Seizures
1.10. Abnormal neurological signs (hypotonia or abnormal level of consciousness) at > 24 hours of age
1.11. Late onset culture-positive (blood or cerebrospinal fluid taken from 7 days to ≤ 28 days of birth) neonatal sepsis including clearly pathogenic organisms and excluding skin organisms (e.g. coagulase-negative staphylococci).
2. Maternal
2.1. Mode of onset of labour
2.2. Mode of delivery
2.3. Duration of time from ruptured membranes to delivery
2.4. Duration of hospital stay
2.5. Change of intended location of childbirth
2.6. Maternal intrapartum anaphylaxis due to IAP
2.7. In a subset of participants for whom detailed data is collected, systemic infection confirmed with a positive blood culture (blood taken from the onset of labour to within 42 days of birth) or suspected maternal sepsis within 42 days of birth as defined by ≥ 1 of the following: A new prescription of IV antibiotics for presumed perineal wound-related infection, endometritis or uterine infection, urinary tract infection with systemic features (pyelonephritis or sepsis) or other systemic infection (clinical sepsis),but NOT antibiotics for any other indication.
2.8. Maternal death, from onset of labour to within 42 days post-partum
2.9. Cause of maternal death
3. Safety Outcome

3.1. The main safety outcome we seek to avoid is neonatal sepsis, which is also the primary outcome that GBS testing aims to reduce. Cases of neonatal sepsis will be collected regularly from routine data sources and an independent neonatal adjudication panel will confirm the diagnosis in a sample of cases.
3.2. Cases of maternal intrapartum anaphylaxis due to IAP will be regularly collected by the teams of participating sites and reported to the trial team on a quarterly basis.
4. Process Outcomes
4.1. Number of women with risk factors for EOGBS infection developing in the baby and which risk factors they have.
4.2. Number of women having a swab taken (of all those eligible for testing), including site of swab (vaginal-rectal, vaginal only) and person performing the swab (self-swab, health care professional swab).
4.3. Number of women who decline a swab when offered (and reasons why)
4.4. Number of women having a swab taken at the appropriate time (of all those swabbed and all those eligible)
4.4.1. For women in antenatal ECM sites: The target time window is > 35 weeks gestation for women without a planned delivery date OR 3-5 weeks prior to the planned delivery date for those women with a planned induction of labour prior to 40 weeks' gestation
4.4.2. For women in intrapartum rapid test sites who are planning to deliver in an obstetric unit (OU) or eligible alongside midwifery-led unit (AMU), the target time window is upon admission, in labour or for induction
4.4.3. For women planning home or freestanding midwifery unit (FMU) deliveries in sites that are allocated to intrapartum rapid testing the target time window is > 35 weeks. See section 11.4 for further details.
4.5. Number of women with a test result available ≥ 4 hours before time of birth
4.6. Number of women with a test result available ≥ 2 hours before time of birth
4.7. Number of women receiving GBS-specific IAP
4.8. Number of women receiving antibiotics for prophylaxis before operative (Caesarean or instrumental) birth
4.9. Number of women receiving intrapartum antibiotics for any other reason
4.10. Number of women with first dose of GBS-specific IAP administered at least 4 hours before childbirth
4.11. Number of women with first dose of GBS-specific IAP administered at least 2 hours before childbirth
4.12. Total dose of administered IAP per woman
4.13. The proportion of women who tested positive for GBS, tested negative for GBS or who did not have an available test result.
4.14. The proportion of failed tests. (For intrapartum rapid testing sites, the number of failed tests will be available from the GeneXpert machine, for ECM sites this may include mislabelled or lost tests)
4.15. Of those who should have been offered IAP according to a positive test result or risk factors, the number of women offered IAP, and the number of women who were not offered IAP
4.16. Number of women declining IAP when offered and reason why.
4.17. Number of women with a negative test result or no documented risk factors who are offered and accept IAP (and reasons)
4.18. Number of babies of mothers who A) tested positive for GBS (testing sites) or B) with documented risk factors (risk factor sites) o whose vital signs and clinical condition were observed for at least 12 hours
4.19. Number of babies of mothers who A) tested positive for GBS (testing sites) or B) with documented risk factors (risk factor sites) o who were investigated for infection and/or had intravenous antibiotics commenced
5. Qualitative Outcomes

5.1. Acceptability, barriers and facilitators to implementation
5.2. The influence of site-specific context and process mechanisms on GBS testing Qualitative outcomes are further described in Section 15.3
6. Economic Outcomes
6.1. Incremental cost per case of early-onset neonatal infection avoided as a result of alternative testing strategies for GBS in pregnancy or labour
6.2. Incremental cost per quality-adjusted life year (QALY) gained as a result of alternative testing strategies for GBS in pregnancy or labour
7. Additional Descriptors
7.1. Descriptors of the dataset population as listed below will be collected and compared:
7.1.1. Maternal age at booking
7.1.2. Parity at booking
7.1.3. Ethnicity
7.1.4. Smoking at booking
7.1.5. Index of Multiple Deprivation for maternal home at the time of childbirth
7.1.6. Number of fetuses (seen at dating ultrasound scan)
7.1.7. Birth order
7.1.8. Neonatal sex
8. Long Term Outcomes
8.1. The exact nature and source of the long-term outcomes will be defined considering current knowledge at the point where further analysis is considered. This would not be before the last baby born within the GBS3 trial has reached 2 years of age and could continue throughout childhood.

———

Previous secondary outcome measures as of 30/03/2022:

1. Neonatal:
1.1 Birth weight
1.2 Perinatal mortality
1.3 Baby death before discharge
1.4 5 minute Apgar
1.5 Gestational age at birth
1.6 Fetal acidaemia (cord arterial pH <7.05)
1.7 Admission for neonatal specialist care (length of stay, level of care)
1.8 Seizures
1.9 Abnormal neurological signs at >24 hours of age (hypotonia or abnormal level of consciousness).
1.10 Late onset culture-positive (blood or cerebrospinal fluid taken from 7 days to ≤ 28 days of birth) neonatal sepsis including clearly pathogenic organisms and excluding skin organisms (e.g. coagulase-negative staphylococci)

2. Maternal:
2.1 Mode of onset of labour
2.2 Mode of delivery
2.3 Duration of time from ruptured membranes to delivery
2.4 Duration of hospital stay
2.5 Change of intended location of childbirth
2.6 Maternal intrapartum anaphylaxis due to intrapartum antibiotic prophylaxis
2.7 In a subset of participants, systemic infection confirmed with a positive blood culture (blood taken from the onset of labour to within 42 days of birth) or suspected maternal sepsis within 42

days of birth as defined by ≥ 1 clinical signs.
2.8 Maternal death, from onset of labour to within 42 days
2.9 Cause of maternal death

3. Safety:
The main safety outcome we seek to avoid is neonatal sepsis, which is also the primary outcome that GBS testing aims to reduce. Cases of neonatal sepsis will be collected regularly from routine data sources and an independent neonatal adjudication panel will confirm the diagnosis in a sample of cases.
Cases of maternal intrapartum anaphylaxis due to IAP will be regularly collected by the teams of participating sites and reported to the trial team on a quarterly basis.

4. Process:
4.1 Number of women with risk factors for EOGBS infection developing in the baby (and which risk factgor)
4.2 Number of women having a swab taken (of all eligible for testing), including site of swab (vaginal-rectal, vaginal only) and person performing the swab (self-swab, health care professional swab).
4.3 Number of women who decline a swab when offered (and reasons why)
4.4 Number of women having a swab taken at the appropriate time (of all those swabbed and all those eligible)
4.5 Number of women with a test result available ≥4 hours before childbirth
4.6 Number of women with a test result available ≥2 hours before childbirth
4.7 Number of women receiving GBS-specific IAP
4.8 Number of women receiving antibiotics for prophylaxis before operative (Caesarean or instrumental) birth
4.9 Number of women receiving intrapartum antibiotics for any other reason
4.10 Number of women with first dose of GBS-specific IAP administered at least 4 hours before childbirth
4.11 Number of women with first dose of GBS-specific IAP administered at least 2 hours before childbirth
4.12 Total dose of administered IAP per woman.
4.13 The proportion of women who tested positive for GBS, tested negative for GBS, or did not have an available test result.
4.14 Proportion of failed tests
4.15 Of those who should have been offered IAP according to a positive test result or risk factors, the number of women offered IAP, and the number of women who were not offered IAP
4.16 Number of women declining IAP when offered (and reasons why)
4.17 Number of women with a negative test or no documented risk factors who are offered and accept IAP (and reasons)
4.18 Number of babies of mothers who tested positive for GBS or had documented risk factors whose vital signs were observed for at least 12 hours
4.19 Number of babies of mothers who tested positive for GBS or had documented risk factors and/or were investigated for infection or had intravenous antibiotics commenced

5. Economic:
5.1 Incremental cost per case of early neonatal sepsis avoided as a result of alternative testing strategies for GBS in pregnancy or labour
5.2 Incremental cost per quality adjusted life year (QALY) gained, as a result of alternative testing strategies for GBS in pregnancy or labour

6. Qualitative:
6.1 Acceptability, barriers and facilitators to implementation,
6.2 The influence of site-specific context and process mechanisms on GBS testing

———

Previous secondary outcome measures as of 24/08/2021:

1. Neonatal:
1.1 Birth weight
1.2 Perinatal mortality
1.3 Baby death before discharge
1.4 5 minute Apgar
1.5 Gestational age at birth
1.6 Fetal acidaemia (cord arterial pH <7.05)
1.7 Admission for neonatal specialist care (length of stay, level of care)
1.8 Seizures
1.9 Abnormal neurological signs at >24 hours of age (hypotonia or abnormal level of consciousness).
1.10 Late onset culture-positive (blood or cerebrospinal fluid taken from 7 days to ≤ 28 days of birth) neonatal sepsis including clearly pathogenic organisms and excluding skin organisms (e.g. coagulase-negative staphylococci)

2. Maternal:
2.1 Mode of onset of labour
2.2 Mode of delivery
2.3 Duration from ruptured membranes to delivery
2.4 Duration of hospital stay
2.5 Change of intended location of childbirth
2.6 Maternal intrapartum anaphylaxis due to intrapartum antibiotic prophylaxis
2.7 Intrapartum or postnatal sepsis within 42 days

3. Safety:
The main safety outcome we seek to avoid is neonatal sepsis, which is also the primary outcome that GBS testing aims to reduce. Cases of neonatal sepsis will be collected regularly from routine data sources and a neonatal adjudication panel will confirm the diagnosis in a sample of cases.

4. Process:
4.1 Number of women with risk factors for EOGBS infection developing in baby
4.2 Number of women having a swab taken (of all eligible for testing)
4.3 Number of women who decline a swab when offered (and reasons why)
4.4 Number of women having a swab taken at the appropriate time (of all those swabbed and all those eligible)
4.5 Number of women with a test result available ≥4 hours before childbirth
4.6 Number of women with a test result available ≥2 hours before childbirth
4.7 Number of women receiving GBS-specific IAP
4.8 Number of women receiving antibiotics for prophylaxis before operative (Caesarean or instrumental) birth
4.9 Number of women receiving antibiotics for any other reason
4.10 Number of women with first dose of GBS-specific IAP administered at least 4 hours before childbirth
4.11 Number of women with first dose of GBS-specific IAP administered at least 2 hours before

childbirth
4.12 Total dose of administered IAP per woman.
4.13 The proportion of women who tested positive for GBS, tested negative for GBS, or did not have an available test result.
4.14 Proportion of failed tests
4.15 Of those who should have been offered IAP according to a positive test result or risk factors, the number of women offered IAP, and the number of women who were not offered IAP
4.16 Number of women declining IAP when offered (and reasons why)
4.17 Number of women offered and accepting IAP, of those with a negative test or no documented risk factors
4.18 Number of babies of mothers who tested positive for GBS or had documented risk factors whose vital signs were observed for at least 12 hours
4.19 Number of babies of mothers who tested positive for GBS or had documented risk factors and had IAP commenced and/or were investigated for infection or had intravenous antibiotics commenced

5. Economic:
5.1 Incremental cost per case of early neonatal sepsis avoided as a result of alternative testing strategies for GBS in pregnancy or labour
5.2 Incremental cost per quality adjusted life year (QALY) gained associated with each strategy, as a result alternative testing strategies for GBS in pregnancy or labour

6. Qualitative:
6.1 Acceptability, barriers and facilitators to implementation,
6.2 The influence of site-specific context and process mechanisms on GBS testing

_____

Previous secondary outcome measures as of 27/10/2020:

1. Neonatal:
1.1 Birth weight
1.2 Perinatal mortality
1.3 Baby death before discharge
1.4 5 minute Apgar
1.5 Gestational age at birth
1.6 Fetal acidaemia (cord arterial pH <7.05)
1.7 Admission for neonatal specialist care (length of stay, level of care)
1.8 Seizures
1.9 Abnormal neurological signs at >24 hours of age (hypotonia or abnormal level of consciousness).
1.10 Late onset culture-positive (blood or cerebrospinal fluid taken from 7 days to ≤ 28 days of birth) neonatal sepsis including clearly pathogenic organisms and excluding skin organisms (e.g. coagulase-negative staphylococci)

2. Maternal:
2.1 Mode of onset of labour
2.2 Mode of delivery
2.3 Duration from ruptured membranes to delivery
2.4 Duration of hospital stay

2.5 Change of intended location of childbirth
2.6 Maternal intrapartum anaphylaxis due to intrapartum antibiotic prophylaxis
2.7 Intrapartum or postnatal sepsis within 42 days

3. Safety:
The main safety outcome we seek to avoid is neonatal sepsis, which is also the primary outcome that GBS testing aims to reduce. Cases of neonatal sepsis will be collected regularly from routine data sources and a neonatal adjudication panel will confirm the diagnosis in a sample of cases.

4. Process:
4.1 Number of women with risk factors for EOGBS infection developing in baby
4.2 Number of women having a swab taken (of all eligible for testing)
4.3 Number of women who decline a swab when offered (and reasons why)
4.4 Number of women having a swab taken at the appropriate time (of all those swabbed and all those eligible)
4.5 Number of women with a test result available ≥4 hours before childbirth
4.6 Number of women with a test result available ≥2 hours before childbirth
4.7 Number of women receiving GBS-specific IAP
4.8 Number of women receiving antibiotics for any other reason (except prophylaxis for caesarean delivery)
4.9 Number of women with first dose of antibiotics administered at least 4 hours before childbirth
4.10 Number of women with first dose of antibiotics administered at least 2 hours before childbirth
4.11 Total dose of administered IAP per woman.
4.12 The proportion of women who tested positive for GBS, tested negative for GBS, or did not have an available test result.
4.13 Proportion of failed tests
4.14 Of those who should have been offered IAP according to a positive test result or risk factors, the number of women offered IAP, and the number of women who were not offered IAP
4.15 Number of women declining IAP when offered (and reasons why)
4.16 Number of women offered and accepting IAP, of those with a negative test or no documented risk factors
4.17 Number of babies of mothers who tested positive for GBS or had documented risk factors whose vital signs were observed for at least 12 hours
4.18 Number of babies of mothers who tested positive for GBS or had documented risk factors and had IAP commenced and/or were investigated for infection or had intravenous antibiotics commenced

5. Economic:
5.1 Incremental cost per case of early neonatal sepsis avoided as a result of alternative testing strategies for GBS in pregnancy or labour
5.2 Incremental cost per quality adjusted life year (QALY) gained associated with each strategy, as a result alternative testing strategies for GBS in pregnancy or labour

6. Qualitative:
6.1 Acceptability, barriers and facilitators to implementation,
6.2 The influence of site-specific context and process mechanisms on GBS testing

———

Previous secondary outcome measures:

1. Neonatal:
1.1 Birth weight
1.2 Perinatal mortality
1.3 5 minute Apgar
1.4 Gestational age at birth
1.5 Fetal acidaemia (cord arterial pH <7.05 or first neonatal pH)
1.6 Neonatal specialist care (length of stay, highest level of care)
1.7 Seizures
1.8 Abnormal neurological signs at >24 hours of age (hypotonia or abnormal level of consciousness).
2. Maternal:
2.1 Mode of onset of labour
2.2 Mode of delivery
2.3 Duration of hospital stay
2.4 Change of intended location of childbirth
2.5 Maternal intrapartum anaphylaxis.
3. Process:
3.1 Maternal risk factors for EOGBS infection developing in baby
3.2 Testing coverage
3.3 Testing at appropriate time
3.4 Test result available at least 4 hours before childbirth
3.5 GBS-specific IAP coverage
3.6 Timing of IAP
3.7 Number of doses of IAP
3.8 Proportion of women who tested negative, positive or had no test
3.9 Identified maternal risk factors at all sites
3.10 Declines and acceptances of IAP
3.11 Number of babies of mothers who tested positive for GBS and had IAP commenced
3.12 Observation time following positive GBS result
3.13 Maternal intrapartum or postnatal sepsis
4. Economic:
4.1 Incremental cost per case of early neonatal sepsis avoided as a result of alternative testing strategies for GBS in pregnancy or labour
4.2 Incremental cost per quality adjusted life year gained associated with each strategy, as a result alternative testing strategies for GBS in pregnancy or labour
5. Qualitative:
5.1 Acceptability, barriers and facilitators to implementation, and on the influence of site-specific context and process mechanisms on GBS testing

Overall study start date
01/04/2019

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 30/03/2022:

1. Inclusion criteria – site level
1.1 Obstetric-led maternity units, and alongside midwifery-led units (AMUs) if able to accept women requiring IAP
1.2 Capable of implementing either the antenatal enriched culture or intrapartum rapid testing strategies with training and support

There will be two levels of eligibility for individual women:
• Testing level – eligibility to have an ECM or rapid test, or be reviewed for risk factors
• Dataset level – eligibility to be included in the dataset for analysis, regardless of whether test performed.
There is no exclusion based on age of women or multiple births.

2. Inclusion criteria – testing level
2.1 In ECM units, all women attending an antenatal clinic at ≥35 weeks' gestation without a planned delivery date, or 3-5 weeks prior to planned induction date for those women with a scheduled induction of labour prior to 40 weeks' gestation.
Women booked for an elective caesarean section should be offered the opportunity of an antenatal ECM test in recognition that a small percentage of women will spontaneously labour and progress to a vaginal delivery before their elective date.
2.2 In rapid test units, all women who experience labour or prelabour rupture of membranes at ≥37 weeks' gestation. Women planning a home birth or in a freestanding midwifery unit (which is not able to offer IAP) can be offered an antenatal rapid test which will be processed on the maternity unit/labour suite at ≥ 35 weeks gestation
2.3 In risk factor units, all pregnant women at ≥24 weeks' gestation

3. Inclusion criteria – dataset level
3.1 In all units, all women giving birth ≥24 weeks' gestation within their unit's study period, regardless of mode of delivery and all her babies
3.2 Women who experience an intrapartum or antepartum stillbirth will be included as they may have had testing for GBS and GBS may be implicated in the aetiology of their stillbirth

4. Inclusion criteria-qualitative study
4.1 Women will be eligible if they are up to 12 weeks postpartum, 16 years of age or older, and reasonably fluent in English
4.2 Women giving birth at:
• a maternity unit allocated a testing strategy, and not a risk factor site.
• FMU/AMU and home births.
4.3 Health Care Professionals will be eligible if they are a registered health professional working in an NHS maternity or neonatal service in one of the 4 NHS recruitment sites

_____

Previous participant inclusion criteria as of 24/08/2021:

1. Inclusion criteria – site level
1.1 Obstetric-led maternity units, and alongside midwifery-led units (AMUs) if able to accept women requiring IAP
1.2 Capable of implementing either the antenatal enriched culture or intrapartum rapid testing strategies with training and support

There will be two levels of eligibility for individual women:
• Testing level – eligibility to have an ECM or rapid test, or be reviewed for risk factors

• Dataset level – eligibility to be included in the dataset for analysis, regardless of whether test performed.
There is no exclusion based on age of women or multiple births.

2. Inclusion criteria – testing level
2.1 In ECM units, all women attending an antenatal clinic at ≥35 weeks' gestation without a planned delivery date, or 3-5 weeks prior to planned induction date for those women with a scheduled induction of labour prior to 40 weeks' gestation
2.2 In rapid test units, all women who experience labour or prelabour rupture of membranes at ≥37 weeks' gestation. Women planning a home birth or in a freestanding midwifery unit (which is not able to offer IAP) can be offered an antenatal rapid test which will be processed on the maternity unit/labour suite at ≥ 35 weeks gestation
2.3 In risk factor units, all women who experience labour or prelabour rupture of membranes at ≥24 weeks' gestation

3. Inclusion criteria – dataset level
3.1 In all units, all women giving birth ≥24 weeks' gestation within their unit's study period, regardless of mode of delivery and all her babies
3.2 Women who experience an intrapartum or antepartum stillbirth will be included as they may have had testing for GBS and GBS may be implicated in the aetiology of their stillbirth

4. Inclusion criteria-qualitative study
4.1 Women will be eligible if they are up to 12 weeks postpartum, 16 years of age or older, and reasonably fluent in English
4.2 Women giving birth at:
• a maternity unit allocated a testing strategy, and not a risk factor site.
• FMU/AMU and home births.
4.3 Health Care Professionals will be eligible if they are a registered health professional working in an NHS maternity or neonatal service in one of the 4 NHS recruitment sites

_____

Previous inclusion criteria as of 27/10/2020:

1. Inclusion criteria – site level
1.1 Obstetric-led maternity units, and alongside midwifery-led units (AMUs) if able to accept women requiring IAP
1.2 Capable of implementing either the antenatal enriched culture or intrapartum rapid testing strategies with training and support

There will be two levels of eligibility for individual women:
• Testing level – eligibility to have an ECM or rapid test, or be reviewed for risk factors
• Dataset level – eligibility to be included in the dataset for analysis, regardless of whether test performed.
There is no exclusion based on age of women or multiple births.

2. Inclusion criteria – testing level
2.1 In ECM units, all women attending an antenatal clinic at ≥35 weeks' gestation without a planned delivery date, or 3-5 weeks prior to planned delivery date for those women with a planned induction of labour prior to 40 weeks' gestation
2.2 In rapid test units, all women who experience labour or prelabour rupture of membranes at ≥37 weeks' gestation. Women planning a home birth or in a freestanding midwifery unit (which

is not able to offer IAP) can be offered an antenatal rapid test on the maternity unit/labour suite at ≥ 35 weeks gestation
2.3 In risk factor units, all women who experience labour or prelabour rupture of membranes at ≥24 weeks' gestation

3. Inclusion criteria – dataset level
3.1 In all units, all women giving birth ≥24 weeks' gestation within their unit's study period, regardless of mode of delivery and all her babies
3.2 Women who experience an intrapartum or antepartum stillbirth will be included as they may have had testing for GBS and GBS may be implicated in the aetiology of their stillbirth

4. Inclusion criteria-qualitative study
4.1 Women will be eligible if they are up to 12 weeks postpartum, 16 years of age or older, and reasonably fluent in English
4.2 Women giving birth at:
• a maternity unit allocated a testing strategy, and not a risk factor site.
• FMU/AMU and home births.
4.3 Health Care Professionals will be eligible if they are a registered health professional working in an NHS maternity or neonatal service in one of the 4 NHS recruitment sites

———

Previous inclusion criteria:

There are eligibility criteria at a site level, which determine which maternity units can participate; at a testing level for women giving birth in testing maternity units; and at a data set level.

1. Inclusion criteria – site level
1.1 Consultant-led maternity units, and alongside midwifery-led units (AMUs) if able to accept women requiring IAP
1.2 Capable of implementing either the antenatal enriched culture or intrapartum rapid testing strategies with training and support

2. Inclusion criteria – testing level
2.1 In ECM units, all women attending an antenatal clinic after 35 weeks' gestation
2.2 In rapid test units, all women who experience labour or prelabour rupture of membranes at > = 37 weeks' gestation
2.3 In risk factor units, all women who experience labour or prelabour rupture of membranes at > = 24 weeks' gestation

3. Inclusion criteria – dataset level
3.1 In all units, all women giving birth > = 24 weeks' gestation within their unit's study period, regardless of mode of delivery and all her live born babies
3.2 Women who experience an intrapartum stillbirth will be included as they may have had testing for GBS and GBS may be implicated in the aetiology of their stillbirth

4. Inclusion criteria-qualitative study
4.1 Women will be eligible if they are up to 12 weeks postpartum, 16 years of age or older, and reasonably fluent in English
4.2 Women giving birth in a maternity unit allocated a testing strategy, and not a usual care unit
4.3 Clinicians will be eligible if they are a registered health professional working in an NHS maternity or neonatal service in one of the 4 NHS recruitment sites

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 320,000; UK Sample Size: 320,000

Total final enrolment
317000

Key exclusion criteria
Current participant exclusion criteria as of 30/03/2022:

1. Exclusion criteria – testing level
1.1 Women who do not provide verbal consent to provide a swab
1.2 Previous baby with GBS infection (early or late onset) and who want IAP (These women can still be offered a test and be given IAP regardless of the result, if requested by the woman)
1.3 Women in preterm labour (suspected, diagnosed, established) at ≤37 weeks gestation should be offered IAP routinely
1.4 In rapid test sites, women who have been admitted for a planned elective caesarean birth, unless labour spontaneously at >=37 weeks and plan not to proceed with elective caesarean birth.
1.5 Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple fetuses
1.6 Known prelabour intrauterine death in the current pregnancy, of a singleton or all multiple fetuses
1.7 In rapid test sites, women who require an emergency caesarean birth but who have intact membranes and are not in labour

2. Exclusion criteria – dataset level
2.1 Known congenital anomaly incompatible with survival at birth, of singleton or all multiple fetuses
2.2 Withdrawal of consent to use data, through the NHS data-opt out (or devolved nation equivalent)

3. Exclusion criteria-qualitative study
3.1 Women will be excluded if their baby died prior to birth or if they lack capacity to give informed consent
3.2 Health Care Professionals will be excluded if they are not currently practising and/or working in an NHS maternity or neonatal service
3.3 Women and Health Care Professionals not receiving care or working in the NHS sites taking part in this study will not be eligible

———

Previous participant exclusion criteria as of 24/08/2021:

1. Exclusion criteria – testing level
1.1 Women who do not provide verbal consent to provide a swab
1.2 Previous baby with GBS infection (early or late onset) and who want IAP (These women can still be offered a test and be given IAP regardless of the result, if requested by the woman)
1.3 Women in preterm labour (suspected, diagnosed, established) at ≤37 weeks gestation should be offered IAP routinely
1.4 Women who have been admitted for a planned elective caesarean birth (Women who have a planned caesarean birth but labour spontaneously should still be offered a test)
1.5 Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple fetuses
1.6 Known prelabour intrauterine death in the current pregnancy, of a singleton or all multiple fetuses
1.7 Women who require an emergency caesarean birth but who have intact membranes and are not in labour

2. Exclusion criteria – dataset level
2.1 Known congenital anomaly incompatible with survival at birth, of singleton or all multiple fetuses
2.2 Withdrawal of consent to use data, through the NHS data-opt out (or devolved nation equivalent)

3. Exclusion criteria-qualitative study
3.1 Women will be excluded if their baby died prior to birth or if they lack capacity to give informed consent
3.2 Health Care Professionals will be excluded if they are not currently practising and/or working in an NHS maternity or neonatal service
3.3 Women and Health Care Professionals not receiving care or working in the NHS sites taking part in this study will not be eligible

———

Previous exclusion criteria as of 27/10/2020:

1. Exclusion criteria – testing level
1.1 Women who do not provide verbal consent to provide a swab
1.2 Previous baby with GBS infection (early or late onset) and who want IAP (These women can still be offered a test and be given IAP regardless of the result, if requested by the woman)
1.3 Women in preterm labour (suspected, diagnosed, established) at ≤37 weeks gestation should be offered IAP routinely
1.4 Women who have been admitted for a planned elective caesarean birth (Women who have a planned caesarean birth but labour spontaneously should still be offered a test)
1.5 Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple fetuses
1.6 Known prelabour intrauterine death, of a singleton or all multiple fetuses
1.7 Women who require an emergency caesarean birth but who have intact membranes and are not in labour

2. Exclusion criteria – dataset level
2.1 Known congenital anomaly incompatible with survival at birth, of singleton or all multiple fetuses
2.2 Withdrawal of consent to use data, through the NHS data-opt out (or devolved nation equivalent)

3. Exclusion criteria-qualitative study
3.1 Women will be excluded if their baby died prior to birth or if they lack capacity to give informed consent
3.2 Health Care Professionals will be excluded if they are not currently practising and/or working in an NHS maternity or neonatal service
3.3 Women and Health Care Professionals not receiving care or working in the NHS sites taking part in this study will not be eligible

_____

Previous exclusion criteria:

1. Exclusion criteria – testing level
1.1 Decline clinical consent to provide a swab
1.2 Previous baby with GBS disease (early or late onset) and who want IAP
1.3 In rapid test units, women who on arrival at the maternity unit are considered likely to deliver they baby within the next hour
1.4 In rapid test units, women in preterm labour (suspected, diagnosed, established), who should be offered IAP routinely
1.5 Known congenital anomaly incompatible with survival at birth, of a singleton or all multiple fetuses
1.6 Known prelabour intrauterine death, of a singleton or all multiple fetuses

2. Exclusion criteria – dataset level
2.1 Congenital anomaly incompatible with survival at birth, of singleton or all multiple fetuses
2.2 Prelabour intrauterine death, of singleton or all multiple fetuses.
2.3 Withdrawal of consent to use data, through the NHS data-opt out

3. Exclusion criteria-qualitative study
3.1 Women will be excluded if their baby died prior to birth or if they lack capacity to give informed consent
3.2 Clinicians will be excluded if they are not currently practising and/or working in an NHS maternity or neonatal service
3.3 Women and clinicians not receiving care or working in the NHS sites taking part in this study will not be eligible

Date of first enrolment
01/10/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre
Northwick Park Hospital
LNWH NHS Trust Watford Road
Harrow
London
United Kingdom
HA1 3UJ

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospital of North Durham
County Durham and Darlington NHS Foundation Trust
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road

Stockton-on-Tees
United Kingdom
TS19 8PE

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Cheriton House
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Healthcare Foundation Trust
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Derriford Hospital
University Hospitals Plymouth NHS Trust
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
West Middlesex University Hospital
Chelsea and Westminster Hospital NHS Foundation Trust
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
Milton Keynes University Hospital
Milton Keynes University Hospital NHS Foundation Trust

Standing Way Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Royal United Hospital Bath
The Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Peterborough City Hospital
North West Anglia NHS Foundation Trust
Edith Cavell Campus
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Nottingham City Hospital
Hucknall Road

Nottingham
United Kingdom
NG5 1PB

Study participating centre
Darlington Memorial Unit
University Hospital of North Durham
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
University Hospital of Hartlepool
North Tees and Hartlepool NHS Foundation Trust
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Friarage Hospital
South Tees Hospitals NHS Foundation Trust
Northallerton
United Kingdom
DL6 1JG

Study participating centre
Hinchingbrooke Hospital
North West Anglia NHS Foundation Trust
Hinchingbrooke Park
Huntingdon
United Kingdom
PE29 6NT

Study participating centre
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Lister Hospital
East and North Hertfordshire NHS Trust
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Royal Derby Hospital
University Hospital of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Queen's Hospital Burton
Belvedere Road
Burton-On-Trent
United Kingdom
DE13 0RB

Study participating centre
Royal Oldham Hospital
Northern Care Alliance
Victoria Unit
Rochdale Rd
Oldham
United Kingdom
OL1 2JH

Study participating centre
Princess Royal University Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
The Tunbridge Wells Hospital and Maidstone Birth Unit
Maidstone and Tunbridge Wells NHS Trust
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Leeds General Infirmary
Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
St James's Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Warrington Hospital
Warrington and Halton Hospitals NHS Foundation Trust
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre

Whittington Hospital
Whittington Health NHS Trust
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Royal Blackburn Hospital
East Lancashire Hospitals NHS Trust
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
East Surrey Hospital
Surrey and Sussex Healthcare NHS Trust
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-Sea
Southend-on-Sea
United Kingdom
SS0 0RY

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust

Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
St. Marys Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road

Reading
United Kingdom
RG1 5AN

Study participating centre
South Warwickshire University NHS Foundation Trust
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
St Georges University Hospitals NHS Foundation Trust
Blackshaw Rd,

London
United Kingdom
SW17 0QT

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham Womens Hospital
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Whipps Cross University Hospital NHS Trust
Whipps Cross Hospital
Whipps Cross Road
London
United Kingdom
E11 1NR

Study participating centre
Newham University Hospital NHS Trust
Newham General Hospital
Glen Road
London

United Kingdom
E13 8SL

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
Chelsea & Westminster Hospital Laboratory
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Epsom and St Helier University Hospitals NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Mersey and West Lancashire Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
University of Wales and Llandough Hospital NHS Trust
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Hywel Dda Health Board (pembrokeshire Office)
Unit 5
Haverfordwest Business Centre
Haverfordwest
United Kingdom
SA61 1SB

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Airedale NHS Trust
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
The Princess Alexandra Hospital NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Pinderfields Hospitals NHS Trust
Trust Hq, Rowan House
Pinderfields General Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4EE

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
Manchester
United Kingdom
M8 5RB

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
Southport and Ormskirk Hospital NHS Trust
Town Lane
Southport
United Kingdom
PR8 6PN

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital

Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Betsi Cadwaladr Uhb
Royal Alexandra Hospital
Marine Drive
Rhyl
United Kingdom
LL18 3AS

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Bedford Hospital
Kempston Road

Bedford
United Kingdom
MK42 9DJ

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research and Innovation
University of Nottingham,
East Atrium, Jubilee Conference Centre
Triumph
Nottingham
England
United Kingdom
NG8 1DH
+44115 84 67906
sponsor@nottingham.ac.uk

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/86/06

Results and Publications

Publication and dissemination plan

The project outputs will be reported on the NIHR awards webpage. The individual component studies will be published together or individually in high-impact peer reviewed journals and by presentation at medical and midwifery conferences locally, nationally and internationally.

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Nottingham Clinical Trials Unit (ctu@nottingham.ac.uk) (added 19/08/2025: after the investigators have published all primary and secondary analyses). Participant-level data will not be available, as it is not permitted by the routine data providers under the terms and conditions under which NCTU receives the data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	02/09/2019	06/01/2020	No	No
Protocol file	version v2.0	17/07/2020	23/10/2020	No	No
Protocol file	version 3.0	26/03/2021	14/09/2021	No	No
Protocol file	version 4.0	15/10/2021	30/03/2022	No	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative study	12/06/2024	20/06/2024	Yes	No
Protocol file	version 5.2	26/07/2023	12/09/2024	No	No
Protocol file	version 6.0	13/12/2023	12/09/2024	No	No
Statistical Analysis Plan	version 1.0	28/02/2024	12/09/2024	No	No
Protocol file	version 6.1	02/07/2024	19/09/2024	No	No
Protocol article		17/06/2025	18/06/2025	Yes	No