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Improving detection of small infants during pregnancy

Submission date
27/06/2016

Recruitment status
No longer recruiting

Registration date
02/11/2016

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stillbirth is when a baby dies in the womb and has to be delivered. It is a tragedy with lifelong consequences for parents and their family and friends. In the UK the number of babies stillborn has not fallen in the past 20 years, and currently affects 1 in every 200 pregnancies. This means that stillbirth in the UK is amongst the highest in Europe. Doctors, midwives and politicians want to change this, and recently reducing stillbirths has been identified as a priority. Most babies that die before birth are normal, but many weigh less than expected. One of the most common reasons for these baby deaths is poor growth in the womb. Often this has gone unnoticed by the doctors and midwives. A baby's growth in the womb relies on the placenta (afterbirth) working well and providing all the nutrients the baby needs. There are many reasons why the placenta does not work well, and in most cases, with the exception of stopping cigarette smoking, there is little the mother can do to improve this. But most small babies are healthy and growing normally. They are small because of genes inherited from their parents. Factors like parents' body size and ethnic background are likely to help doctors and midwives work out which babies are small but growing normally and which are small because their placenta is not working well. These babies could be at risk of being stillborn. Previously, a large study has suggested that a package known as Growth Assessment Protocol (GAP), which takes these factors into account, has reduced the stillbirth rates in three regions of the UK. However, there are many other possible reasons other than the GAP that could have led to the reduction in stillbirths in this study. The aim of this study is to look at the impact of the GAP, and whether it really does reduce stillbirths, so that doctors, midwives and policy makers will know whether they should put resources in place to use GAP in all NHS hospitals.

Who can participate?
Pregnant women delivering their baby at a participating hospital.

What does the study involve?
Participating maternity units are randomly allocated to one of two groups. Those in the first group will provide care according to the GAP programme (immediate implementation). For participating women, this involves a standardized way of having their risk of having a baby that is too small for its age assessed at 12 weeks and screening for small infants after 24 weeks using customized centiles (measurements) according to GAP principles. Those in the second group

receive usual care, which could involve having their risk of having a baby that is too small for its age assessed at 12 weeks and screening methods for small babies after 24 weeks bases as per routine care. Participants in both groups are followed up until delivery by the clinical team in their hospital to find out if they had a small baby.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Maternity units across 13 NHS Trusts in England (UK)

When is the study starting and how long is it expected to run for?
January 2015 to October 2018

Who is funding the study?
Tommys (UK)

Who is the main contact?
Dr Matias Costa Vieira
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
20296

Study information

Scientific Title
The DESiGN Trial: Detection of small for gestational age fetus (SGA) – a cluster randomised controlled trial to evaluate the effect of the Growth Assessment Protocol (GAP) programme

Acronym
DESiGN

Study objectives
The GAP programme improves the detection of small for gestational age fetuses when compared to currant clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Bloomsbury Research Ethics Committee, 29/02/2016, ref: 15/LO/1632

Study design
Randomised; Interventional; Design type: Screening, Diagnosis, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and sexual medicine

Interventions
Hospitals will be randomized to one of two groups. The method of allocation is the random permutation of clusters within each of two equally sized strata; clusters are divided in the two strata according to their size (deliveries per year in 2013-2014) and then randomized to either early or delayed implementation.

Early implementation arm: The GAP programme will be immediately implemented with training and the use of protocols consistent with the principles of GAP. Women in this study arm will be risk assessed for SGA and managed as per GAP protocol. Low risk women will be seen routinely in antenatal clinic. At these visits standardised FH measurements will be performed from 28 weeks. In high risk women serial ultrasounds after 24 weeks will be recommended. Customised FH and ultrasound charts will be generated at the first trimester ultrasound visit. FH measurements will be plotted on the customised FH chart. In low risk women any deviation in growth on these charts will result in recommendation for ultrasound measurement. Estimated fetal weight (EFW) from ultrasound measurements will be plotted on customised EFW charts for both low or high risk women whenever an ultrasound is done.

Delayed implementation arm: Women will have a risk assessment according to routine practice (if available) and screening for SGA according to local protocol (if available) and use of population charts as reference for diagnosis of SGA in antenatal ultrasounds. GAP will be introduced after the data collection for outcomes.

Majority of participating women will not be required to return for additional research visits but some women in the study will be approached by the research team and invited to take part in interviews to explore the experience of receiving care in line with GAP programme. Source of data will vary according to the outcome assessed. Most of the data will be acquired from routine hospital data. This will include manly electronic records but also review of some clinical notes. Data will be obtained from hospital maternity electronic systems which record antenatal, ultrasound, intrapartum, postnatal and neonatal information. Data obtained manually from clinical notes will be entered into a trial database. For the implementation component of the study primary data collection from interviews and focus groups will be performed.

Intervention Type
Other

Primary outcome(s)
Detection rate of SGA infants measured by ultrasound after 24 weeks* is assessed using data from the maternity and ultrasound system between months 13 to 18 of study.

* The antenatal charts used for ultrasound detection (numerator) will depend on the allocation arm of the trial. The denominator for the estimation of detection in each arm of the trial will be the same population of SGA infants (birthweight <10th centile) by both customised and population

Key secondary outcome(s))
1. Detection rate (sensitivity), specificity, false positive and false negative of SGA by customised centiles measured by ultrasound after 24 weeks
2. Detection rate (sensitivity), specificity, false positive and false negative of SGA by population centiles measured by ultrasound after 24 weeks

Clinical outcomes:
Neonatal:
1. Gestational age measured in weeks at birth
2. Birthweight measured in grams at birth
3. Head circumference measured in centimeters at birth
4. Apgar score <7 measured using Apgar scale at birth
5. Metabolic acidosis defined as an arterial cord ph<7.1 at birth
6. Rate or need of respiratory support in delivery room at birth
7. Rate of neonatal intensive care after birth
8. Length of stay in neonatal intensive care unit (NICU) measured in days
9. Level of care needed in NICU
10. Rate of major neonatal morbidity defined as one or more of the following: intraventricular haemorrhage, supplementary oxygen requirements > 28 days, necrotizing enterocolitis, sepsis, retinopathy of prematurity
11. Length of stay in transitional care measured in days
12. Rate of neonatal morbidity defined as one or more of the following: hypothermia, hypoglycaemia, nasogastric tube feeding
13. Rate or stillbirth (antepartum and intrapartum)

14. Rate of neonatal death (early and late)
15. Rate of neonatal death before discharge (after 28 days of birth)

Maternal:
1. Rate of induction of labour measured at birth
2. Rate of caesarean section measured at birth
3. Rates of postpartum haemorrhage (>1000ml) measured at birth
4. Rate of severe perineal trauma (3rd / 4th degree tear) measured at birth
5. Length of stay in hospital measured in days
6. Method of breast feeding measured at discharge

Health economics outcomes:
1. Number of ultrasound scans after 24 weeks measured at delivery (as average of ultrasound per women)
2. Number of antenatal clinic / antenatal day unit measured at delivery (as average of ultrasound per women)

Process evaluation of implementation outcomes:
1. Proportion of staff trained measured at the end of training period (expected to be at month 6 of study)
2. Proportion of staff assessed for GAP training at the end of training period (expected to be at month 6 of study)
3. Proportion of women assessed with GAP programme measured throughout the study by review of notes of a sample of participants
4. Adherence to SGA risk stratification and management protocols and missed case analysis measured throughout the study and assessed by hospital level data (data available from risk assessment)

Outcomes for other methods of assessments of antenatal detection of SGA:
1. Detection rate of SGA (birthweight<5th centile) measured by ultrasound after 24 weeks
2. Detection of SGA infants measured as clinical detection before birth (review of notes)

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Hospitals:
1. Willing to implement GAP
2. Willing to participate in the trial

Patients:
1. Pregnant women
2. Delivering at one of the participating hospitals during the study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Hospitals that have fully implemented or will not be introducing GAP.

Date of first enrolment
01/12/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

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

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
St George's Healthcare NHS Trust
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Kingston Hospital NHS Trust
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Croydon Health Services NHS Trust
London Road
Thornton Heath
United Kingdom
CR7 7YE

Study participating centre
Imperial College Healthcare NHS Trust
Pread Street
London
United Kingdom
W2 1NY

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
North West London Hospitals NHS Trust
Watford Road

Harrow
United Kingdom
HA1 3UJ

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

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
North Middlesex University Hospital NHS Trust
Sterling Way
London
United Kingdom
N18 1QX

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

Sponsor information

Organisation
Comprehensive Clinical Trials Unit at UCL

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Tommy's Baby Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Stillborn and Neonatal Death Charity

Alternative Name(s)
SANDS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised data will be stored centrally by the sponsor (Clinical Trials Unit at University College London).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/09/2022	06/09/2022	Yes	No
Results article	Health economics outcomes	07/07/2022	09/01/2024	Yes	No
Protocol article	protocol	04/03/2019	07/03/2019	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	sub-study results	08/03/2021	10/03/2021	Yes	No