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Avoiding sexual intercourse in late pregnancy and the risk of Group B Streptococcus carriage in the mother

Submission date
28/01/2026

Recruitment status
Recruiting

Registration date
30/01/2026

Overall study status
Ongoing

Last Edited
29/01/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Group B Streptococcus (GBS) is a bacterium that can live in the vagina or anus without causing symptoms in pregnant women. In 2020, worldwide, an estimated 19.7 million women in late pregnancy carry GBS in the vagina or anus. Women carrying GBS can pass the bacteria to their newborn child, causing a very serious infection called early-onset invasive neonatal GBS disease (EONGBS), which occurs within the first 6 days of life. About 231,800 babies (0.17% of live births) worldwide were affected by EONGBS, with around 91,900 infant deaths (39.6% of those infected) and approximately 37,100 survivors (16% of those infected) left with moderate or severe long-term brain or developmental impairment.

In a recent study from this centre, GBS carriage in late pregnancy is more commonly found when the woman also reports sexual intercourse within the previous 2 weeks, possibly due to intercourse changing the natural balance of bacteria in the vagina. The same study shows that GBS is present in about 41% of women in late pregnancy.

Screening for GBS carriage is usually done at 35-37 weeks of pregnancy, about 3-5 weeks before anticipated delivery. Women found to carry GBS are given appropriate antibiotics in labour to help reduce the risk of passing GBS to their baby during childbirth.

This study aims to persuade women at 32-34 weeks of pregnancy to avoid vaginal intercourse with the hope that this can reduce the chance of them carrying GBS during labour and passing the bacteria to their baby. This study will compare advice to avoid vaginal intercourse in late pregnancy to standard care of providing no medical advice for or against sex in late pregnancy.

Who can participate?
Women between 32 and 34 weeks of pregnancy attending the antenatal clinic for routine follow-up will be screened and invited to take part in this study if they fulfil the conditions to participate.

What does the study involve?
1) Screened patients will be provided with the Patient Information Sheet (PIS) and questions will be invited from them and responded to by the recruiting provider.
2) The patient's partner will also be provided with an information sheet to fully inform them of the study intervention, as sexual intercourse is a couple activity.
3) Written informed consent will be obtained from all participants and their partners.
4) Investigators, not involved in recruitment, clinical care, or data collection, will do the following:

a. Generate the randomisation sequence in random blocks of 4 or 8 with further randomisation within these blocks,using an online randomizer sealedenvelop.com
b. The randomization sequence is then sealed within numbered opaque envelopes.
c. These envelopes are then assigned in strict sequence, the lowest numbered envelope still available to the newest recruit.
d. The numbered envelope is then unsealed to reveal the allocated intervention to the participant.

• Active intervention: Advice group: Advice leaflet and verbal reinforcement to abstain from sexual intercourse at least until their appointment for GBS screening at 35-37 weeks.
or
• Control group: Standard care (no specific advice on sexual activity to birth)

5) All participants will be given a sexual intercourse diary to record sexual intercourse daily from recruitment until their 35-37 weeks appointment for GBS screening.
6) A convenient appointment at least 3 weeks from the recruitment date will be offered to all participants for their GBS screening at 35-37 weeks.
7) At the GBS screening, a swab will be inserted into the lower vagina and rotated two to three times to pick up secretions. The same swab will then be inserted into the anal opening and the earlier process is repeated.
8)The swab will then be placed into transport media before transfer to the laboratory. The transport medium is the non-nutritive Amies medium (with or without charcoal).
9) GBS will be sought using an enrichment culture medium at our hospital laboratory.
10)Results from the laboratory will be informed to the participants as soon as they are known.

What are the possible benefits and risks of participating?
Benefits
All participants will be provided with GBS screening free of charge. Late pregnancy GBS screening is not standard care at our centre.

Risks
Identification of GBS carriage in the participants will result in participants being offered antibiotics to reduce the risk of Early Onset Neonatal GBS disease. Because only a small proportion of GBS-carrying participants pass on GBS disease to their babies, many participants will be unnecessarily exposed to antibiotics to prevent one case of EONGBS disease.

Where is the study run from?
The study will be conducted in Antenatal Clinic University Malaya Medical Centre (UMMC), Malaysia.

When is the study starting and how long is it expected to run for?
March 2026 to March 2027.

Who is funding the study?
The Department of Obstetrics & Gynaecology, University Malaya Medical Centre (UMMC), Malaysia.

Who is the main contact?
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Study information

Scientific Title
Sexual intercourse abstinence and ano-vaginal Group B Streptococcus carriage in late pregnancy: a randomized controlled trial

Acronym
ABSTAIN-GBS Study

Study objectives
To evaluate maternal anovaginal GBS carriage rate at 35-37 weeks by advising abstinence from sexual intercourse from 32-34 weeks compared to standard care with no specific sexual intercourse advice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/12/2025, Medical Research Ethics Committee, University of Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2025723-15384

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Maternal Group B Streptococcus carriage at 35-37 weeks of pregnancy.

Interventions
Randomization will be conducted using a computerized sequence generator. The sequence will be generated in random blocks of 4 or 8 (1:1 ratio) via https://www.sealedenvelope.com/simple-randomiser/v1/lists by a co-investigator not involved in trial recruitment. Participants will be assigned to one of two trial arms by opening a numbered, sealed, opaque envelope, with the lowest numbered envelope still available assigned to the latest recruit.
Participants at 32-34 weeks of pregnancy will be randomised to:

(A) Active intervention: Advice group: Advice leaflet and verbal reinforcement to abstain from sexual intercourse until at least 35-37 weeks of pregnancy.

Or

(B) Control group: Standard care (no specific advice on sexual activity)

1. All participants will be given a Patient Information Sheet (PIS) about the study. The PIS is neutral concerning the causation between sexual intercourse and anovaginal GBS carriage.

2. All participants will be given a convenient appointment for GBS screening at 35-37 weeks at least 3 weeks from the recruitment at 32-34 weeks.

3. All participants will be given a sexual intercourse diary to record sexual intercourse daily from recruitment until their appointment for GBS screening.

4. All participants will be provided with their GBS screening result as soon as it is known, so that participants can inform their care provider when in labour.

Intervention Type
Behavioural

Primary outcome(s)
1. GBS carriage rate measured using a combined vaginal–rectal swab culture with standard microbiological methods at 35-37 weeks

Key secondary outcome(s)
1. Labor/Delivery : Preterm birth (<37 weeks gestation) measured using data recorded in the electronic medical record, and retrieved at hospital discharge

2. Labor/Delivery : Prelabour Rupture of Membrane measured using a clinical diagnosis of rupture of membranes prior to onset of labour as documented in electronic medical records at one time point

3. Labor/Delivery: Induction of labour (Methods of IOL) measured using data recorded in electronic medical record, retrieved at hospital discharge

4. Labor/Delivery: GBS antibiotic prophylaxis in labour measured using data on the administration of intrapartum antibiotics for GBS prophylaxis as recorded in electronic medical record, retrieved at hospital discharge

5. Labor/Delivery: Therapeutic antibiotic in labour measured using data on the administration of antibiotics in labour for clinical indications other than GBS prophylaxis as recorded in electronic medical record, retrieved at hospital discharge

6. Labor/Delivery: Intrapartum fever during labor measured using maternal body temperature ≥38.0 °C as recorded in electronic medical record, retrieved at hospital discharge

7. Labor/Delivery: Mode of delivery measured using a recording of the delivery type: spontaneous vaginal, instrumental, or caesarean section as recorded in electronic medical record, retrieved at hospital discharge

8. Labor/Delivery: Estimated delivery blood loss (in mililitres) measured using data recorded in electronic medical record, retrieved at hospital discharge

9. Labor/Delivery: Maternal Intensive Care Unit admission (Indication for admission) measured using data recorded in the electronic medical record, retrieved at hospital discharge

10. Neonatal : APGAR score at 1 and 5 minutes after delivery measured using data recorded in electronic medical record, retrieved at hospital discharge

11. Neonatal : Birth weight (in grams) measured using data recorded in electronic medical record, retrieved at hospital discharge

12. Neonatal : Umbilical cord arterial blood pH at birth measured using as recorded in electronic medical record, retrieved at hospital discharge

13. Neonatal : Neonatal sepsis during neonatal hospital stay measured using clinical diagnosis of neonatal sepsis as recorded in electronic medical record, retrieved at hospital discharge

14. Neonatal : Early Onset Neonatal GBS infection within the first 7 days after birth measured using a clinical diagnosis of neonatal sepsis with microbiological confirmation of Group B Streptococcus as recorded in electronic medical record at one time point

15. Neonatal : Admission for presumed sepsis during neonatal hospital stay measured using data recorded in electronic medical record at one time point

16. Neonatal : Neonatal intensive care unit admission (indication) during neonatal hospital stay measured using data recorded in electronic medical record at one time point

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. 32-34 weeks gestation.
2. Adult (18 years old and above)

3. Singleton pregnancy
4. Live fetus
5. Sexually active (vaginal sex at least once a week in the last week)
6. Partner's agreement for participation and recording of sexual activity information in the study

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Culture proven GBS colonization or infection (from any site) in current pregnancy
2. Antibiotics use in the last 4 weeks (any indication)
3. Preterm prelabour rupture of membrane
4. Significant medical/antenatal complications (cardiac disease, renal disease, recurrent vaginal bleeding in pregnancy, etc)
5. Proven/suspected vaginal infection in the last 4 weeks
6. Contraindication to sexual intercourse (placenta praevia, current vaginal bleeding, etc)

Date of first enrolment
01/03/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type

Funder Name
Department of Medicine, University of Malaya

Alternative Name(s)
Faculty of Medicine - Universiti Malaya, Medicine Department - Faculty of Medicine - Universiti Malaya, medicineumalaya, University of Malaya Faculty of Medicine

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available