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Sleep aids to reduce pre-caesarean anxiety

Submission date
13/10/2025

Recruitment status
No longer recruiting

Registration date
21/11/2025

Overall study status
Completed

Last Edited
13/11/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This study will test whether simple sleep aids can lower anxiety before a planned caesarean section by helping pregnant patients sleep better in the days leading up to surgery.

Many people feel anxious before surgery, and this worry can worsen pain, nausea, and overall recovery after the operation. Non-drug options are attractive because they are low risk and have less side effects. Improving sleep is linked to better mental health and less anxiety in general. This study aims to find out if wearing an eye mask and earplugs at night can improve sleep and, in turn, reduce anxiety before a planned caesarean section compared with a sham headband control.

Who can participate?
Adults with a singleton, term pregnancy (37 weeks or more) who have a planned caesarean section scheduled 3 to 14 days ahead are eligible to be assessed for the study. People will not be able to take part if there are known psychiatric or anxiety disorders, known sleep disorders, significant hearing or vision problems, fetal anomalies, or anticipated surgical complications such as placenta accreta or extensive adhesions.

What does the study involve?
Participants are randomly assigned by computer to one of two groups: eye mask and earplugs each night, or an elastic headband as a sham control, during the days before surgery until hospital admission for the caesarean section. Everyone will wear a wrist actigraph that looks like a watch during sleep to objectively measure sleep and will also keep a simple daily sleep diary of bedtimes, wake times, and estimated sleep duration. On admission for surgery, the team will collect the device and diary, and participants will complete a short questionnaire about preoperative anxiety (Perioperative Anxiety Scale7) and rate satisfaction with the sleep aid. After the surgery, further outcomes such as pain on the day after surgery, symptoms of nausea, vomiting and dizziness, and breastfeeding status at six weeks will be collected from records or brief follow-up calls as described in the protocol and information sheet.

What are the possible benefits and risks of participating?
Potential benefits include better sleep and lower anxiety before surgery, and possibly a more comfortable recovery, though direct personal benefit cannot be guaranteed. Risks are expected to be minimal. Eye masks, earplugs, and headbands are commonly used and are not anticipated

to cause harm, but any unexpected issues will be reviewed by the department's research oversight panel.

Where is the study run from?
The study is managed by the Department of Obstetrics and Gynaecology at University of Malaya Medical Centre (UMMC) (Malaysia), with recruitment in the antenatal clinic and inpatient assessment at the antenatal ward upon admission for the planned caesarean section.

When is the study starting and how long is it expected to run for?
January 2025 to August 2026

Who is funding the study?
The Department of Obstetrics and Gynaecology, UMMC will cover study-related costs such as devices, data management, and analysis.

Who is the main contact?
Dr Chew Siang Wen (Department of Obstetrics and Gynaecology, UMMC), 22060979@siswa.um.edu.my

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Siang Wen Chew

Contact details
Universiti Malaya Medical Centre, Jalan Profesor Diraja Ungku Aziz, Seksyen 13
Petaling Jaya
Malaysia
50603
+60 03-7949 4422, 010-9111500
22060979@siswa-old.um.edu.my

Additional identifiers

Protocol serial number
2025119-14622

Study information

Scientific Title
Eye mask and earplugs as sleep aids to reduce pre-caesarean anxiety: a randomised sham-controlled trial

Acronym
SERENE

Study objectives

To evaluate eye mask and earplugs as sleep aids in improving anxiety 24 hour before planned caesarean section

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 22/07/2025, UMMC–Medical Research Ethics Committee (UMMCMREC) (UMMCMREC Secretariat, Menara Utama/Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya, Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 037949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 2025119-14622

Primary study design
Interventional

Study design
Randomized controlled trial single centre parallel group

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre operative anxiety prior to a planned caesarean section

Interventions
The allocated intervention will take place during the period leading up to the date of scheduled caesarean section.
All participants will be provided with the ActiGraph wGT3X-BT device (Pensacola, Florida, USA) and instructed on its use. The device is to be worn like a wristwatch, and participants are asked to wear it to sleep at night up until the day of their planned caesarean section. They will be told to record in a sleep dairy their ‘time to bed’ and ‘time out of bed’ as well as their own estimated total sleep time.
Participants randomised to EMEP shall wear the eye mask and earplugs before going to sleep each night. If the patient has to mobilise, EMEP can be removed and to be replaced on returning to bed.
Participants randomised to the control arm shall wear the elasticated headband before going to sleep each night and to remove it on awakening to get out of bed. The headband serves as a sham/placebo control.
Upon admission for planned caesarean section, the sleep diary and actigraph watch will be retrieved and participant’s PAS-7 scores and satisfaction post intervention recorded. The ‘Time to bed’ and ‘Time out of bed’ (TOB) recorded will be used for calculation of sleep duration using the ActiLife software later.

The randomisation sequence will be generated using https://www.sealedenvelope.com/simple-randomiser/v1/lists, in blocks of 4 or 8, in 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Allocation will be sealed within a numbered opaque envelope. Randomisation will be implemented using strict sequential opening of the lowest-numbered remaining sealed envelopes for the latest recruit.

Intervention Type
Behavioural

Primary outcome(s)
Anxiety score using PAS-7 questionnaire assessed within 24 hours of planned caesarean section.

Key secondary outcome(s)
1. Day 1 post operative pain score on movement (assessed on day 1 post caesarean section: 0-10 numerical rating scale)
2. Symptom assessment (assessed on day 1 post caesarean section: Yes/No response) on Nausea, Vomiting, Dizziness
3. Maternal satisfaction with intervention (assessed on day 1 post caesarean section: 0-10 numerical rating scale)
4. Post operative analgesia use (assessed on hospital discharge: through electronic medical records)
5. Mode of anaesthesia (assessed on hospital discharge: through electronic medical records)
6. Estimated blood loss (assessed on hospital discharge: through electronic medical records)
7. ICU admission (assessed on hospital discharge: through electronic medical records)
8. ICU admission indication (assessed on hospital discharge: through electronic medical records)
9. APGAR score at 1 minute (assessed on hospital discharge: through electronic medical records)
10. APGAR score at 5 minute (assessed on hospital discharge: through electronic medical records)
11. Birth Weight (assessed on hospital discharge: through electronic medical records)
12. Umbilical cord arterial blood pH (assessed on hospital discharge: through electronic medical records)
13. Umbilical cord arterial blood base excess (assessed on hospital discharge: through electronic medical records)
14. Neonatal admission (assessed on hospital discharge: through electronic medical records)
15. Neonatal admission indication(assessed on hospital discharge: through electronic medical records)
16. Length of hospital stay [admission until discharge] (assessed on hospital discharge: through electronic medical records)
17. DASS-21 score (assessed 6 weeks after delivery: through telephone assessment using DASS-21)
18. Exclusively breastfeeding status [“Exclusive breastfeeding means that the infant receives only breast milk. No other liquids or solids are given – not even water – with the exception of oral rehydration solution, or drops/syrups of vitamins, minerals or medicines”: WHO](assessed 6 weeks after delivery: through telephone assessment using Yes/No responses)

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Planned caesarean section (minimum of 3 days up to maximum of 14 days in advance)
2. Singleton pregnancy
3. Term pregnancy (≥37 weeks at planned caesarean section)
4. Viable pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Known psychiatric illnesses (e.g., depression, bipolar disorder, schizophrenia, etc.)
2. Known sleep disorders
3. Known anxiety disorders
4. Known hearing or vision impairments
5. Gross fetal anomalies
6. Perioperative complications anticipated (e.g., morbidly adherent placenta spectrum, anticipated major intraabdominal adhesions, etc.)

Date of first enrolment
08/10/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Melaya Medical Centre/ Pusat Perubatan Universiti Malaya
Jln Profesor Diraja Ungku Aziz, Seksyen 13, 50603 Petaling Jaya, Wilayah Persekutuan Kuala Lumpur
Petaling Jaya
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. 22060979@siswa-old.um.edu.my

Where will the data be kept?
Manual records: stored in secured locker with a lock in Obstetrics and Gynaecology Department UMMC. The key will be kept only by primary investigator
Digital records" password-protected computers accessible only to researchers

Who will have access to the research data?
Principle investigator and approved co-investigators

How long will the data be kept? (suggestion: at least 7 years)
Minimum of 7 years after completion of the study

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2		10/11/2025	No	Yes
Protocol file	version 2	06/08/2025	10/11/2025	No	No