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Eye mask and earplugs to improve sleep after epidural analgesia during labour at night in first-time mothers

Submission date
15/01/2025

Recruitment status
No longer recruiting

Registration date
22/01/2025

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Pregnancy and Childbirth

[X] 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
First-time mothers often perceive their labour to be more painful as their labour usually takes longer. These patients often choose an epidural for labour pain relief as it is the most effective method. Adequate sleep may help to shorten labour. Eye masks and earplugs have been shown to improve the sleep of patients cared for in an intensive care unit or high-dependency care unit by reducing background light and sound. An actigraphy watch will be used to objectively measure sleep parameters. After getting pain relief from an epidural sited at night, wearing an eye mask and earplugs (EMEP) may block labour room light and noise and help restore night sleep, which may be important for labour and birth. This study's main purpose is to evaluate if using EMEP can lengthen restorative night sleep in first-time mothers-to-be who need an epidural.

Who can participate?
First-time mothers-to-be aged 18 years and over who have received epidural labour pain relief, in early labour (<6 cm dilated), term gestation (≥37 weeks) and normal fetal heart rate tracing

What does the study involve?
Participants are randomly allocated to use eye masks and earplugs (EMEP) as sleep aids and to wear the actigraph watch (intervention group), or to wear the actigraph watch only (control comparison group). Both groups are to record in a diary the times when sleep is attempted. The study intervention period is complete when the participants start pushing for birth or at the arrangement for a caesarean delivery. Participants will be asked to rate their score using a 0-10 scale on 'satisfaction with your sleep during labour' and 'satisfaction with pain relief from the epidural during labour' after delivery

What are the possible benefits and risks of participating?
Eye masks and earplugs (EMEP) may lengthen sleep and improve the perceived experience of labour, but it is unclear if there will be other benefits such as shorter labour or an easier birth. Major benefits are not anticipated.
EMEP use is not expected to carry risk or cause harm. However, it is not implausible that some

women may feel deprived having slept through their labour and may not then fully perceive the entire natural labour experience.

Where is the study run from?
University of Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
August 2024 to December 2025

Who is funding the study?
University of Malaya Medical Centre (Malaysia)

Who is the main contact?
Dr Lela Nadia Khalid, lelanadiakhalid@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
MECID.No: 2024825-14120

Study information

Scientific Title
Eye mask and earplugs to improve sleep after epidural analgesia during nulliparous labour at night: a randomised controlled trial

Study objectives
The use of eye mask and earplugs as sleep aids will lengthen sleep after epidural labour pain relief at night

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/12/2024, Medical Research Ethics Committee University Of Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 (0)379493209; iresearch@ummc.edu.my), ref: MECID.No: 2024825-14120

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Sleep duration during labour after epidural analgesia at night

Interventions
Patient recruitment will take place in the Labour Ward of University of Malaya Medical Centre (UMMC) at epidural analgesia or within an hour of its insertion timed from 1800 to 0600 hours. Consented patients will be randomised to eye mask and earplugs (EMEP) plus actigraph watch or actigraph watch only as control. Participants randomised to EMEP shall wear the eye mask and earplugs when trying to sleep. They will also wear the actigraph watch from the epidural to pushing or decision for caesarean delivery. Participants randomised to the control arm shall wear the actigraph watch from the epidural to pushing or decision for caesarean delivery. Attempt to sleep characterised by ‘time to bed’ to ‘time out of bed’ shall be recorded and the recording of these times repeated if there were multiple attempts to sleep. The sleep diary and actigraph watch will be retrieved after delivery for actigraphy analysis. Care providers may interrupt sleep as clinically indicated at any time, to make observations, get responses or effect interventions.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eye mask, ear plugs, actigraph watch

Primary outcome(s)
Sleep duration measured using actigraphy data assessed after delivery

Key secondary outcome(s)
1. Intervention to delivery interval as recorded from the patient’s electronic medical record after delivery
2. Maternal satisfaction with sleep during labour measured using a 0-10 numerical rating scale after delivery
3. Mode of delivery from patient’s electronic medical record after delivery
4. Indication for operative delivery (Caesarean and instrumental vaginal delivery) from patient’s electronic medical record after delivery

5. Perineal condition from patient’s electronic medical record after delivery
6. Estimated delivery blood loss from patient’s electronic medical record after delivery
7. Birth weight from patient’s electronic medical record after delivery
8. Apgar score at 1 and 5 minutes from offspring’s electronic medical record after delivery
9. Umbilical cord artery blood pH and BE from offspring’s electronic medical record after delivery
10. Neonatal admission from offspring’s electronic medical record after delivery
11. Indication for neonatal admission from offspring’s electronic medical record after delivery

Completion date
16/12/2025

Eligibility

Key inclusion criteria
1. 18 years old and above
2. Nulliparous (no prior pregnancy >22 weeks)
3. Singleton pregnancy
4. 37 weeks of gestation and above
5. Epidural analgesia sited from 1800H to 0600H
6. Cervical dilatation less than 6 cm
7. Normal fetal heart rate tracing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Need for frequent monitoring
2. Known sleep disorders
3. Major hearing (using hearing aids) or visual impairment (refractive errors acceptable)
4. Gross fetal anomalies
5. Intrauterine fetal death

Date of first enrolment
31/03/2025

Date of final enrolment
16/10/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Of Malaya Medical Centre (UMMC)
Pusat Perubatan Universiti Malaya
Jalan Profesor Diraja Ungku Aziz
Seksyen 13
KUALA LUMPUR
Malaysia
50603

Sponsor information

Organisation
University of Malaya Medical Centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University of Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/08/2024	21/01/2025	No	Yes
Protocol file		08/08/2024	21/01/2025	No	No