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Eye-masks and earplugs as sleep aids to reduce blood pressure in pregnancy

Submission date
06/02/2023

Recruitment status
No longer recruiting

Registration date
17/02/2023

Overall study status
Completed

Last Edited
05/03/2025

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
Short sleep duration in pregnancy is common and tends to worsen into late pregnancy. The risk of pregnancy-induced high blood pressure increases with sleep deprivation. This study aims to evaluate the effects of the use of eye masks and earplugs as sleep aids on blood pressure in women with borderline high blood pressure and short sleep duration in late pregnancy over a one-week study period.

Who can participate?
Adult women in late pregnancy with sleep deprivation and pre-hypertension

What does the study involve?
In this study, participants will be assigned by a computer to use an eye mask and earplugs for sleep or normal care (no eye mask and earplugs). Participants will be given a wristwatch-like device (ActiGraph) to wear continuously for the week and be required to record their blood pressure in a blood pressure diary twice a day. This needs to be done before bedtime at night and after awakening in the morning using the automated blood pressure machine provided and as instructed. Participants will complete a sleep questionnaire at recruitment and at the end of the study.

What are the possible benefits and risks of participating?
The use of eye masks and earplugs may increase sleep duration but there is at present no evidence to show that pregnancy outcomes will improve. The impact of the use of an eye mask and earplugs on blood pressure in pregnancy is not established. The use of eye masks and earplugs is not expected to have any adverse effect.

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

When is the study starting and how long is it expected to run for?
November 2022 to March 2024

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

Who is the main contact?
Dr Shahira Aqilah Zulkifli, shahiraqilah@gmail.com (Malaysia)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Eye-masks and earplugs as sleep aids to reduce blood pressure in pregnancy: A randomised controlled trial

Study objectives
Eye masks and earplugs as sleep aids will reduce blood pressure in women with pre-hypertension (suboptimal blood pressure) and short night sleep duration in late pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2023, Medical Research Ethics Committee, University Malaya Medical Centre, (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +603-79493209 ext 2251; ummc-mrec@ummc.edu.my), ref: 20221215-11811

Study design
Parallel-arm randomized control trial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied
Pre-hypertension in late pregnancy in mothers with sleep deprivation

Interventions
This is an interventional randomized controlled study in which participants will be assigned by a computer (only revealed after the opening of an envelope after mothers consent to participate) into two groups for seven consecutive days of the study:
1. Wear an eye mask and ear plugs as sleep aids and wear an actigraphy watch
2. No sleep aids and wear an actigraphy watch

At recruitment participants will complete a sleep questionnaire.
During the one-week study period, participants will need to:
1. Use the eye mask and earplugs for sleep OR normal care (no eye mask and earplugs) for sleep, as randomly allocated
2. Wear the wristwatch-like device (ActiGraph) continuously for the week, most importantly during sleep (night sleep as well as daytime naps)
3. Record their sleep in a Sleep diary as the time they go to bed to sleep and the time they wake to get out of bed for both night sleep as well as any daytime naps. This information is needed by the actigraphy software to work out your sleep duration when in bed for sleep.
4. Record their blood pressure in a Blood Pressure diary twice a day, before bedtime at night and after awakening in the morning using the automated blood pressure machine provided and as instructed

After the one-week study period, participants will need to:
1. Return the Actigraph device for sleep data to be downloaded and analysed
2. Return the Sleep and Blood Pressure diaries
3. Complete the sleep questionnaire again

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Commercially available sleep aids (eye masks and ear plugs), actigraph watch (wGT3X-BT)

Primary outcome measure
1. Systolic blood pressure measured using an automated blood pressure machine from recruitment to during the intervention period
2. Diastolic blood pressure measured using an automated blood pressure machine from recruitment to during the intervention period

Secondary outcome measures
Maternal outcome:
1. Mean arterial pressure measured using an automated blood pressure machine from recruitment to during the intervention period
2. Pregnancy-induced hypertension (systolic BP ≥ 140 and/or diastolic ≥ 90 mmHg) on 2 occasions at least 4 hours measured using an automated blood pressure machine apart during

the intervention period
3. Actigraphy derived-night sleep duration measured using data recorded in the watch app during the intervention period
4. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at recruitment and at the end of the intervention period
5. Pregnancy outcome measured using data recorded in patient medical notes:
5.1. Labour induction
5.2. Mode of delivery
5.3. Peri-delivery blood loss

Neonatal outcome measured using data recorded in patient medical notes after birth:
1. Birth weight
2. Cord arterial blood pH and base excess
3. Health evaluation measured using APGAR scoring at 1 and 5 minutes after birth
4. Neonatal intensive care unit (NICU) admission

Overall study start date
01/11/2022

Completion date
06/03/2024

Eligibility

Key inclusion criteria
1. Blood pressure within suboptimal/pre-hypertension range (systolic 120-139 and/or diastolic 80-89 mmHg)
2. Self-reported sleep of less than 6 hours
3. Gestation 34-36 weeks
4. Age more or equal to 18 years old
5. Singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
140 participants

Key exclusion criteria
1. Anticipated delivery in the next week
2. Significant visual and/or hearing impairment

3. On antihypertensives for gestational hypertension or chronic hypertension
4. Known sleep disorders: Chronic insomnia, sleep apnoea
5. Known psychiatric disorders: Depression, schizophrenia etc.
6. Known major medical disorders: Diabetic Mellitus type 1 or 2, SLE, thyroid disorders, epilepsy, heart diseases etc.
7. Inability/unwillingness to use an eye mask and earplugs
8. Inability/unwillingness to use ActiGraph wGT3X-BT device
9. BMI >35
10. Active smoker
11. Current alcohol consumption
12. Multipara with co-sleeping child/children
13. Night shift workers
14. Night caretaker of other family members
15. Gross fetal anomalies
16. Intrauterine fetal death

Date of first enrolment
07/03/2023

Date of final enrolment
28/06/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universiti Malaya Medical Centre

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
01/10/2024

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	version 1.0	14/12/2022	16/02/2023	No	Yes