ISRCTN99834087 https://doi.org/10.1186/ISRCTN99834087

Can an eye mask and earplugs compared to a headband help to improve night sleep and spontaneous vaginal delivery in nulliparas?

Submission date
28/05/2019

Recruitment status
No longer recruiting

Registration date
11/06/2019

Overall study status
Completed

Last Edited
25/05/2023

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
75% of pregnant women experience some form of sleep disruption during pregnancy. The rate of sleep disturbances also increases across trimesters, ranging from 13% in the first trimester, 19% in the second, and 66% in the third. Lack of sleep in the third trimester has a detrimental effect on pregnancy outcomes. Women who reported less than 6 hours of sleep per night during the last month of pregnancy had a significantly longer mean duration of labour and a higher rate of caesarean births. Women who slept less than 7 hours at night are at increased risk of developing gestational diabetes, gestational hypertension and preterm birth. Eye masks and earplugs may help to improve spontaneous vaginal delivery among women who have never given birth before (nulliparas) in their third trimester. The aim of this study is to assess the impact of eye masks and earplugs compared to a headband as sleep aids among 34 to 36 weeks nulliparas.

Who can participate?
Nulliparas who attend the Antenatal Clinic at University Malaya Medical Centre, who sleep for less than 6 hours a night

What does the study involve?
Participants are randomly allocated to the intervention group or the sham method group. The intervention group are provided with eye masks and earplugs to wear when they go to bed at night up until the delivery. They may remove the eye masks and earplugs temporarily if they wake up from sleep at night. The sham method group are provided with an elasticated headband to wear when they go to bed at night up until the delivery. The headband shall be placed on their forehead loosely. At the end of 2 weeks, participants receive a call from the investigator to assess their sleep quality using a questionnaire. Participants are followed up until delivery to assess the rate of spontaneous vaginal delivery.

What are the possible benefits and risks of participating?
Patients may have improved sleep with sleeping aids and thus improved spontaneous vaginal delivery. There are no risks involved.

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?
June 2019 to July 2020

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

Who is the main contact?
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Additional identifiers

Protocol serial number
NMRR-19-590-47577

Study information

Scientific Title
A randomized controlled trial on eye mask and earplugs compared to headband to improve night sleep and spontaneous vaginal delivery in nulliparas

Study objectives
Use of earplugs and eye masks at 34-36 weeks during night time will improve spontaneous vaginal delivery among nulliparas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/5/2019, Medical Research Ethics Committee of University Malaya Medical Centre (UMMC, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; Tel: +60 (0)3 7949 3209; Email: umrec@um.edu.my), ref: MREC ID NO: 201936-7199

Primary study design
Interventional

Study design
Prospective randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Spontaneous vaginal delivery among nulliparas

Interventions
Nulliparas who are at 34 - 36 weeks who attend the antenatal clinic in UMMC will be approached regarding this study. A patient information sheet will be provided for those who fulfil the initial eligibility criteria. Those who agree to participate will be asked to provide written consent. Randomisation with the intention to treat with a specific intervention or placebo sham method will follow. They will be randomised into two groups, interventional group or placebo using a sham method, based on a randomisation sequence generated using random.org in a random block of 4 or 8 sequence, generated by an investigator not involved in the recruitment process. Randomisation is by the opening of a sealed opaque and numbered envelope with lowest available envelope assigned in strict order.

Interventional Group:
Participants are provided with eye masks and earplugs to wear when they go to bed at night up till the delivery. They may remove the eye masks and earplugs temporarily if they wake up from sleep at night. At the end of 2 weeks, participants will receive a call from the investigator regarding sleep quality using a sleep questionnaire. They will be followed up until the delivery to analyse the spontaneous vaginal delivery as that is the primary objective.

Placebo Group:
Participants are provided with an elasticated headband to wear when they go to bed at night up until the delivery. The headband shall be placed on their forehead loosely. At the end of 2 weeks, participants will receive a call from the investigator regarding their sleep quality using a sleep questionnaire. They will be followed up until the delivery to analyse the spontaneous vaginal delivery as that is the primary objective.

Patients' labour and neonatal outcomes will be collected after they deliver.

Intervention Type
Other

Primary outcome(s)
Spontaneous vaginal delivery assessed using questionnaire in the data collection form upon delivery

Key secondary outcome(s)
Night sleep assessed using questionnaire form after 2 weeks

Completion date
30/07/2020

Eligibility

Key inclusion criteria
1. Nulliparous (no prior pregnancy ≥ 20 weeks)
2. 34-36 weeks of gestation
3. Self-reported sleep less than 6 hours
4. Singleton pregnancy
5. Access to the phone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
234

Key exclusion criteria
1. Patients with known pre-existing sleep disorders: chronic insomnia, sleep apnea
2. Patients with known pre-existing psychiatric disorders, e.g. depression, schizophrenia, etc
3. Patients with underlying medical disorders: SLE, thyroid disorders, epilepsy, heart disease

4. Planned caesarean delivery (e.g. placenta praevia , breech, maternal request)
5. Night shift workers or night care commitments
6. Active smoker
7. Current alcohol consumption
8. Maternal obesity >class II (BMI>35)
9. Intrauterine death
10. Care taker of other family members
11. Gross fetal anomaly

Date of first enrolment
16/12/2019

Date of final enrolment
16/06/2020

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti, Lembah Pantai
Kuala LLumpur
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50603

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University 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?
Results article		24/05/2023	25/05/2023	Yes	No
Protocol file	version V2	04/12/2017	11/06/2019	No	No