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Can ear plugs and eye masks improve sleep among pregnant mothers?

Submission date
28/12/2017

Recruitment status
No longer recruiting

Registration date
15/01/2018

Overall study status
Completed

Last Edited
27/02/2023

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
Sleep disturbances are very common among pregnant ladies especially in their third trimester. Short sleep duration has been associated with poor labour outcomes. Drug treatments to improve sleep duration are limited. Eye masks and ear plugs are commonly used to improve sleep especially among air travellers. They are proven to increase sleep duration significantly among ICU patients. Pregnant ladies may be more sensitive to sound and light. The aim of this study is to find out whether using eye masks and ear plugs to block those stimuli increases night sleep duration.

Who can participate?
Pregnant women (34 – 36 weeks of gestation), with a single pregnancy, who have never given birth before, and who sleep for less than 6 hours a night

What does the study involve?
Participants are provided with a watch-like actigraphy device and taught how to use it. They need to wear it when they sleep at night for 7 consecutive nights. After 7 days, they return to the antenatal clinic and their sleep data is retrieved from the device. They can proceed with the study only if 3 days of usable readings are recorded. They are then randomly allocated into two groups. In the first group participants are provided with eye masks and ear plugs to wear when they go to bed at night for 7 consecutive nights. They may remove the eye masks and ear plugs temporarily if they wake up at night. In the second group participants are provided with an elasticated headband to wear when they go to bed at night for 7 consecutive nights. The headband shall be placed on their forehead loosely. At the end of 7 days, participants return to the antenatal clinic and their sleep data is analysed. Information about their labour and their baby is obtained from the participants' hospital delivery notes after they have delivered. At the end of the study, participants' satisfaction with their sleep quality is assessed.

What are the possible benefits and risks of participating?
The sleep aids may increase night sleep duration in the third trimester, and improve their labour and their baby's outcome. The sleep aids used are very common and unlikely to pose any risks.

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

When is the study starting and how long is it expected to run for?
January 2018 to December 2018

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Ear plugs and eye mask to improve night sleep duration in nulliparas: a randomised control trial

Study objectives
Ear plugs and eye masks will increase night sleep duration among nulliparas with short self-reported night sleep duration in their late third trimester.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Malaya Medical Center Ethics Committee, 14/12/2017,MREC ID NO: 2017105-5648

Study design
Single-centre randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep disorders among pregnant ladies

Interventions
Nulliparas who are at 34 – 36 weeks who attend Antenatal clinic in UMMC and reported night sleep duration of 5 hours or less on average in the last 1 month will be informed regarding this study. The patient information sheet will be provided for those who fulfilled initial eligible criteria. Those who agreed to participate will be asked to provide written consent, and agree to participate in this study, will be recruited.

They will be provided with Actisleep and taught on methods to use it. They need to wear it when they sleep at night 7 consecutive nights. Time in bed (TIB) and Time out of bed (TOB) need to be recorded every night. After 7 days, they need return to Antenatal clinic, their sleep data will be retrieved from the Actisleep device. They can proceed with the study only if 3 days of usable readings are recorded. 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 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 sealed opaque and numbered envelope with the lowest available envelope assigned in strict order.

Interventional group: eye masks and ear plugs
Subjects are provided with eye masks and ear plugs to wear when they go to bed at night for 7 consecutive nights. Time in bed (TIB) and time out of bed (TOB) needs to be recorded every

night. They may remove the eye masks and ear plugs temporarily if they wake up from sleep at night. At the end of 7 days, subjects will return to the antenatal clinic and have the Actisleep analysed and returned to the investigator.

Placebo group
Subjects are provided with an elasticated headband to wear when they go to bed at night for 7 consecutive nights. The headband shall be placed on their forehead loosely. Time in bed (TIB) and time out of bed (TOB) needs to be recorded every night. At the end of 7 days, subjects will return to the antenatal clinic and have the Actisleep analysed and returned to the investigator.

Patients labor and neonatal outcomes will be analysed after they have delivered. At the end of the study, subjects' satisfaction on their sleep quality will be assessed based on Likert satisfaction scale.

Intervention Type
Device

Primary outcome measure
Night sleep duration, measured using actigraphy (Actisleep Device) over 7 consecutive nights

Secondary outcome measures
1. Wake after sleep onset (WASO) and sleep efficiency (SE), measured using actigraphy (Actisleep Device) over 7 consecutive nights
2. Labour outcomes, obtained from hospital delivery notes after delivery:
2.1. Maternal:
2.1.1. Mode of delivery
2.1.2. Indication for Caesarean delivery
2.1.3. Need for labor induction: prostaglandin or amiotomy
2.1.4. Peridelivery blood loss
2.1.5. Epidural requirement
2.2. Fetal
2.2.1. Birth weight
2.2.2. Cord pH and base excess
2.2.3. Apgar score at 5 minutes
2.2.4. Neonatal admission and indication
3. Maternal perception of sleep quality with sleep aid, measured using Likert scale at the end of the study

Overall study start date
01/01/2018

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Nulliparous
2. 34 – 36 weeks of gestation
3. Self-reported night sleep of less than 6 hours
4. Singleton pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
50

Total final enrolment
56

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 diseases etc
4. Night shift workers
5. Active smoker
6. Current alcoholic consumption
7. Obesity > class II (BMI > 35)
8. Intrauterine death

Date of first enrolment
01/02/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Kuala Lumpur
Malaysia
49200

Sponsor information

Organisation
Obstetrics and Gynaecology Department, University Malaya Medical Center

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Center, Department of Obstetrics and Gynaecology

Results and Publications

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

Intention to publish date
01/06/2019

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?
Protocol file	version V2	04/12/2017	16/01/2018	No	No

Results article	05/12/2022	27/02/2023	Yes	No