

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

|                                        |                                                       |                                                                                                              |
|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/12/2017   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>15/01/2018 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>27/02/2023       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> 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?  
Dr Ik Hui Teo  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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

## Sponsor details

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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? |
|-------------------------------|------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> | version V2 | 04/12/2017   | 16/01/2018 | No             | No              |

[Results article](#)

05/12/2022

27/02/2023

Yes

No