ISRCTN17526076 https://doi.org/10.1186/ISRCTN17526076

Improvement in night sleep duration and the effect on diabetes in pregnancy

Submission date
02/07/2021

Recruitment status
No longer recruiting

Registration date
14/07/2021

Overall study status
Completed

Last Edited
16/02/2024

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
Pregnancy is associated with changes in sleep structure. Both abnormally long and short duration of sleep at night will have an impact on sugar metabolism and may affect bodily functions in the long term. This study will focus on improving the duration of sleep at night and reducing the risk of developing gestational diabetes in pregnancies less than 34 weeks.

Who can participate?
Pregnant women between the age of 18 to 40 years old, who report a duration of sleep of fewer than 7 hours

What does the study involve?
The participants will be divided into two groups, the intervention group and the control group. All participants will need to fill the questionnaire before and after the study. All the participants will be provided with an ActiGraph wGT3X-BT device and a sleep diary. The intervention group will be provided with an eye mask and earplugs and need to wear them for 7 consecutive nights. After completion of 7 days, all participants regardless of the intervention group or control group will need to return the device for data retrieval and a glucose test will be performed.

What are the possible benefits and risks of participating?
The use of an eye mask and earplugs is not expected to cause any harm to the pregnancy. If proven to be effective, the use of these simple interventions such as eye masks and earplugs will improve the duration of sleep at night and reduce the risk of developing diabetes in pregnancy. This can be identified as a modifiable risk factor and thus reducing the risk of developing gestational diabetes mellitus among pregnant women who are at risk.

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?
May 2021 to September 2022

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

Who is the main contact?
Dr Normala Binti Mohammad Som
normala.som@ummc.edu.my

Contact information

Type(s)
Scientific

Contact name
Dr Normala Mohammad Som

Contact details
T.B.G 132 Kg Kuantan
Klang
Malaysia
41300
+60 (0)164144953
normala.som@ummc.edu.my

Type(s)
Scientific

Contact name
Dr Jesrine Hong Gek Shan

Contact details
Jln Profesor Diraja Ungku Aziz, Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)177202689
jesrine@um.edu.my

Type(s)
Scientific

Contact name
Dr Nurulhuda binti Ahmad Sani

ORCID ID
https://orcid.org/0000-0002-5340-2201

Contact details
University of Malaya Medical Centre
UMMC
Jalan Profesor Diraja Ungku Aziz

Kuala Lumpur
Malaysia
59100
+60 (0)3 79492049
huda.sani@ummc.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MECID.No:202157-10120

Study information

Scientific Title
Eye-masks and earplugs to improve night sleep duration in pregnancy and the effect on the oral glucose tolerance test: a randomized trial

Acronym
EMEPOG

Study objectives
Home use of eye masks and earplugs will increase actigraphy-derived night sleep duration among nulliparas and multiparas and this will improve the fasting and 2-hour glucose tolerance test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, Medical Research Ethics Committee University of Malaya Medical Centre (Jln Professor Diraja Ungku Aziz, 50603, Wilayah Persekutuan Kuala Lumpur, Malaysia; +603 (0) 7949 8473; email: not applicable), ref: 202157-10120

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Glucose tolerance in pregnancy

Interventions
The eligibility and suitability of the patient will be identified when presented to the antenatal clinic. Once identified, participants will be asked to fill in the Pittsburgh Sleep Quality Index (PSQI). The researchers will verbally counsel them regarding the trial and written consent will be obtained if they agree to participate. Participants will then be provided with the Patient Information Sheet (PIS). Participants fill in the PSQI and will be randomized into two groups (intervention group and control group). The intervention group will be provided with an eye mask, earplugs and sleep diary and the control group will be provided with a sleep diary.

All participants will then be provided with the ActiGraph wGT3X-BT device and instructed on its use. The device is to be worn like a wristwatch and participants are asked to wear it continuously for 7 consecutive nights on their dominant wrist. Participants need to perform an oral glucose tolerance test (OGTT) upon returning the device and complete a modified PSQI. Participant's details and all the necessary information will be transcribed onto the Case Report Form (CRF).

Intervention Type
Behavioural

Primary outcome(s)
1. Night sleep duration measured using the Actigraph wGT3X-BT device at the end of week 1
2. Fasting blood sugar and 2-hour post glucose tolerance test measured using oral glucose tolerance test performed at the end of week 1

Key secondary outcome(s))
1. Actigraphy-derived Wake After Sleep Onset (WASO) and actigraphy-derived sleep efficiency measured using the Actigraph wGT3X-BT device at the end of week 1
2. Sleep satisfaction measured using the Pittsburgh Sleep Quality Index (PSQI) during recruitment, and the modified Pittsburgh Sleep Quality Index at the end of week 1

Completion date
14/09/2022

Eligibility

Key inclusion criteria
1. Self-reported sleep less than 7 hours
2. Gestation less than 34 weeks
3. Singleton pregnancy
4. Aged 18 to 40 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
40 years

Sex
Female

Total final enrolment
240

Key exclusion criteria
1. Inability to use eye mask and earplugs
2. Inability to use ActiGraph wGT3X-BT device
3. Pre-existing sleep disorders: chronic insomnia, sleep apnea
4. Pre-existing psychiatric disorders: depression, schizophrenia etc
5. Pre-existing medical disorders: diabetic mellitus, systemic lupus erythematosus, thyroid disorders, epilepsy, heart diseases etc
6. Active smoker
7. Current alcohol consumption
8. Multipara with co-sleeping child/children
9. Night shift workers
10. Night care-taker of other family members
11. Gross fetal anomalies
12. Intrauterine fatal death
13. Body mass index (BMI) ≥35 kg/m²

Date of first enrolment
19/07/2021

Date of final enrolment
24/08/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Jalan Professor Diraja Ungku Aziz
Wilayah Persekutuan Kuala Lumpur
Malaysia
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 datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Tan Peng Chiong (pctan@um.edu.my). Individual participant data will be available, particularly, individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices). Other documents that will be available include the Trial Protocol. Data will be available beginning 3 months and ending 5 years following article publication, to investigators whose proposed use of the data has been approved by an independent review committee identified for the purpose of individual participant data meta-analysis only. Consent from participants was required and obtained. The data will be anonymously generated.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/08/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			04/08/2021	No	No