ISRCTN39001643 https://doi.org/10.1186/ISRCTN39001643

Massage by an electric massage chair compared to nitrous oxide gas as first-line pain relief in labour

Submission date
23/04/2024

Recruitment status
No longer recruiting

Registration date
29/04/2024

Overall study status
Completed

Last Edited
26/04/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Labour pain is ranked high when compared to other painful life experiences but the memory is short-lived and 90% who experienced severe pain in labour, found the experience satisfactory three months later. Labour is more prolonged and perceived to be more painful despite greater analgesia use for first-time labour. As labour progresses, labour pain increases.

There are different ways to help ease pain during labour. Amongst the drug-based pain relievers, nitrous oxide gas (Entonox – also known as “gas and air”) provides some pain relief and is often offered as the first line in our centre. Opioid injections also help and an epidural is considered the most effective analgesic. Most women prefer a graduated approach to pain relief in labour, escalating to an epidural as needed.

Manual massage by hand can also reduce labour pain as well as the length of labour, It can improve women's sense of control and emotional experience of labour. Recently, a preliminary study has shown that mechanical massage by an electric massage chair can also provide pain relief in labour

An electric massage chair is a reusable resource with low operating cost and requires limited care provider training, so it has intrinsic advantages over traditional manual massage by hand for labour pain relief.

We aim to evaluate using a massage chair against inhalation of nitrous oxide gas as first- line labour pain relief in women in their first labour based on the hypothesis that massage chair use will be non-inferior to the need for another analgesic in labour and will increase maternal.

Who can participate?
Adult women in labour at term gestation in their first ongoing pregnancy, requesting pain relief and willing to accept the use of either a massage chair or the inhalation of nitrous oxide gas for first-line pain relief as randomly assigned can participate.

What does the study involve?
Participants randomised to the use of an electric massage chair are instructed to sit in the massage chair with the ‘full-body’ massage program switched on for at least 30 minutes. They can continue to use the chair for as long as they want until the active second stage of labour. Participants randomised to nitrous oxide gas inhalation through a mouthpiece are instructed on its use; holding the mouthpiece themselves, putting their lips around the flat, white tube, making an air- tight seal, and taking slow deep breaths, starting just as a contraction begins. Once the contraction is over, the mouthpiece can be removed to breathe room air. They can continue to use the nitrous oxide for as long as they want until the active second stage of labour. Participants may request stronger analgesics including opioids and an epidural on their perception of
need or medically advised due to developments in labour.

What are the possible benefits and risks of participating?
An electric massage chair use may generate greater maternal satisfaction, have fewer side effects and be no less effective in relieving pain than the established nitrous oxide gas as labour pain reliever. On the other hand, the reverse can happen. Stronger analgesics are available on request for all participants.

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?
January 2024 to November 2025

Who is funding the study?
Department of Obstetrics and Gynecology, Faculty of Medicine, University Malaya, Malaysia

Who is the main contact?
1. Dr Dayallini, s2135472@siswa.um.edu.my
2. Prof. Dr Tan Peng Chiong, pctan@um.edu.my

Contact information

Type(s)
Principal investigator

Contact name
Dr Dayallini Malaipan

Contact details
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 178912754
s2135472@siswa.um.edu.my

Type(s)
Public, Scientific

Contact name
Prof Tan Peng Chiong

Contact details
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 123052970
pctan@um.edu.my

Additional identifiers

Protocol serial number
20231017-12962

Study information

Scientific Title
Electric massage chair compared to nitrous oxide gas as first-line analgesic in nulliparous labour: a randomised controlled trial

Study objectives
We aim to evaluate mechanical massage by the electric massage chair to nitrous oxide gas (Entonox) as first-line labour pain relief in patients at their first labour based on the hypotheses that:
1. The massage will be non-inferior to the need for another analgesic, and
2. Will increase maternal satisfaction as a first-line pain reliever

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/01/2024, University of Malaya Medical Centre Medical Research Ethics Committee (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 379498473; ummc-mrec@ummc.edu.my), ref: 20231017-12962

Primary study design
Interventional

Study design
Interventional single centre unmasked parallel-group randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
First-line labour pain relief in nulliparas

Interventions
Participants who have provided informed written consent will be randomised in a 1-to-1 ratio. Randomisation will be effected by opening the lowest numbered sealed opaque envelope available to reveal the allocated intervention for the latest recruit. The randomisation sequence is generated in random blocks of 4 or 8 using an online randomiser by an investigator not involved in the recruiting. Due to their obvious nature, no attempt will be made to mask the interventions.
As a first-line analgesic in labour, randomisation to:

1. Application of mechanical massage using the electric massage chair (active intervention) [Participants randomised to the use of an electric massage chair are instructed to sit in the massage chair with the 'full-body' massage program switched on for at least 30 minutes. They can continue to use the chair for as long as they want until the active second stage of labour.]
OR

2. Application of nitrous oxide gas (Entonox) inhalation (control intervention)
[Participants randomised to nitrous oxide gas inhalation through a mouthpiece are instructed on its use; holding the mouthpiece themselves, putting their lips around the flat, white tube, making an air-tight seal, and taking slow deep breaths, starting just as a contraction begins. Once the contraction is over, the mouthpiece can be removed to breathe room air. They can continue to use the nitrous oxide for as long as they want until the active second stage of labour.]
Participants may request stronger analgesics including opioids and an epidural on their perception of need or medically advised due to developments in labour.

Intervention Type
Mixed

Primary outcome(s)
1. Additional analgesic in labour (from the medical record)
2. Maternal satisfaction with their allocated first-line pain reliever (by Numerical rating scale [NRS] 0-10, completely dissatisfied to completely satisfied - asked after the delivery)

Key secondary outcome(s)
1. Pain score (by NRS 0-10, a higher score denoted greater pain – asked at 30, 60 and 120 minutes)
2. Time from intervention start to time of (from the medical record):
2.1. initiation of other labour analgesia (if any)
2.2. initiation of epidural (if any)
2.3. second stage of labour
2.4. delivery
3. Epidural analgesia during labour (from the medical record)
4. Opiate analgesia during labour (from the medical record)
5. Side effects during labour (asked after delivery)
5.1. Vomiting
5.2. Dizziness
5.3. Drowsiness
5.4. Back pain
5.5. Body pain
5.6. Back bruising
6. Mode of delivery (from the medical record)

7. Indication for operative delivery (from the medical record)
8. Perineal condition after delivery (from the medical record)
9. Estimated delivery blood loss (from the medical record)
10. Fever (from the medical record)
11. Birthweight (from the medical record)
12. Apgar score at (from the medical record) 1 minute and 5 minutes
13. Umbilical cord artery blood (from the medical record):
13.1. pH
13.2. base excess
14. Neonatal admission (from the medical record)
15. Indication for admission (from the medical record)
16. For first-line labour pain relief in the future, I prefer to use (Asked after delivery): -Massage chair OR Nitrous oxide (Gas – Nitrous oxide)

Completion date
01/11/2025

Eligibility

Key inclusion criteria
1. Admitted to the ward for birth (for labour or induction of labour)
2. Planned vaginal delivery
3. Accepts either nitrous oxide or massage chair as first-line labour analgesia
4. Nulliparous (no prior delivery > 20 weeks)
5. Age ≥ 18 years
6. Gestational age of ≥ 37 weeks
7. Singleton pregnancy
8. Cephalic presentation
9. Reassuring fetal heart rate tracing
10. Estimated fetal weight of 2 to 4 kg
11. Requesting labour pain relief

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria

1. Contraindication or unsuitability for nitrous oxide or massage chair
2. Known major fetal malformations
3. COVID 19 infection or SARS-CoV2 positive

Date of first enrolment
01/06/2024

Date of final enrolment
01/11/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

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 raw data generated during and/or analyzed during the current study are/will be available for authorised IPD meta-analysis upon request from Dr Dayallini (s2135472@siswa.um.edu.my) subject to institutional review board approval

IPD sharing plan summary

Available on request