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Pain relief for the first stage of labour using an electric massage chair

Submission date
04/07/2022

Recruitment status
No longer recruiting

Registration date
03/08/2022

Overall study status
Completed

Last Edited
13/11/2023

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 is typically painful, especially during the first labour. Many women require pain relief in labour. Epidural, opiate-type drugs and inhaling gas and air are commonly offered forms of pain relief. These methods have potential undesired effects on the mother and her baby. Massage by a human therapist is an effective pain-relieving technique during labour. However, trained massage therapists are not available in the usual labour ward setting, the service is labour intensive and likely costly.

We plan to evaluate the use of a commercially available electric massage chair capable of providing a full body massage on its pain-relieving potential during the labour of women expecting their first baby as proof of the concept of mechanical massaging being effective.

Who can participate?
Women who have not had a previous pregnancy beyond 20 weeks (nulliparous), who are at full term, and who were admitted to the labour ward in the first stage of labour

What does the study involve?
Participants in one group will receive 30 minutes on a commercially procured electric massage chair that provides a full body massage program with the massaging function switched on and then 30 minutes with the massaging function switched off. Participants in a second group will do the opposite and receive 30 minutes on the electric massage chair with the massaging function switched off and then 30 minutes with the massaging function switched on. The groups will be compared using a Visual Numerical Rating Scale (VNRS) and questionnaire to score perceived pain.

What are the possible benefits and risks of participating?
There is no significant benefit or risk anticipated as all participants are exposed to the massage chair as this trial has a cross-over design. The massage provided by the chair may or may not be effective in providing pain relief. No significant harm is anticipated from the intervention with the massage chair as routine labour monitoring and care are continued during the massage.

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 2022 to March 2023

Who is funding the study?
Universiti Malaya (Malaysia)

Who is the main contact?
Nadia Mazia (Malaysia)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.0

Study information

Scientific Title
Massage chair as pain relief in the first stage of labour in nulliparas: A randomised cross-over trial (MASPAR)

Acronym
MASPAR

Study objectives
The objective of this proposed study is to evaluate the effect of massage chair therapy on labour pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/6/2022, Medical Research Ethics Committee of The University of Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3-79493209; iresearch@ummc.edu.my), ref: 2022323-11097

Study design
Randomized cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Pain relief in labour

Interventions
Nulliparous women at term in the first stage of labour will be randomised to 30 minutes on the electric massage chair with the massaging function switched on then cross over to 30 minutes with the massaging function switched off or 30 minutes on the electric massage chair with the massaging function switched off then cross over to 30 minutes with the massaging function switched on. A commercially procured electric massage chair that provides a full body massage program will be used.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electric massage chair

Primary outcome measure
Pain score (0 to 10 numerical rating scale) measured using an 11-point visual numerical rating scale (VNRS) (0 scoring as no pain at all to 10 as the worst pain imaginable) immediately after each 30-minute session on the massage chair with the massage function switched on or off

Secondary outcome measures
Maternal outcomes:
1. Mode of delivery measured by reviewing patient's notes after delivery
2. Intervention to delivery interval measured by reviewing patient's notes after delivery
3. Epidural anaesthesia in labour measured by reviewing patient's notes after delivery
4. Likert scale response to the questionnaire on pain relieving effectiveness of the massage by the massage chair after delivery

Neonatal outcomes:
4. Umbilical cord arterial pH measured by reviewing patient's notes at birth
5. Apgar score at 1 and 5 minutes measured by reviewing patient's notes at birth
6. Neonatal admission measured by reviewing patient's notes at birth

Overall study start date
07/01/2022

Completion date
02/03/2023

Eligibility

Key inclusion criteria
1. Nulliparous (no previous pregnancy beyond 20 weeks)
2. Aged 18 years old and over
3. 37 weeks gestation and over

4. Singleton pregnancy
5. Cephalic presentation
6. Reassuring cardiotocogram in last 1 hour
7. Cervical dilation 4-8 cm
8. Contraction ≥ 3 in 10 minutes
9. Pain score ≥ 5 (0-10 NRS)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. High-risk pregnancies (pre-eclampsia, active hemorrhage)
2. No prior pain relief (epidural, opiates, nitrous oxide or pain relief device)
3. Meconium-stained liquor
4. Oxytocin dose adjustment in the last hour
5. Bladder catheter in place
6. Delivery anticipated within the next 2 hours

Date of first enrolment
04/08/2022

Date of final enrolment
23/02/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre (UMMC)
Lembah Pantai
Kuala Lumpur
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
01/01/2024

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