ISRCTN16026114 https://doi.org/10.1186/ISRCTN16026114

Mechanical massage using an electric massage chair and the onset of coming in of breastmilk in first-time mothers

Submission date
16/02/2024

Recruitment status
No longer recruiting

Registration date
19/02/2024

Overall study status
Completed

Last Edited
27/02/2024

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
Hand (manual) massage especially along the back and foot after birth has been shown to speed up the first coming in of breast milk and of milk production. Hand massage is time consuming and a learnt skill. The electric mechanical massage chair is reusable, simple to operate and consistent in the massage it delivers but it has not been explored if it is effective. Delayed or perceived inadequate milk production can cause problems with the start or maintenance of breastfeeding of the baby.

WHO and UNICEF recommend that infants be exclusively breastfed for the first 6 months of life.

First time mothers take a longer time to first breastfeeding attempt, are more likely to have eight or fewer feeding attempts in the first 24 hours, to report early breastfeeding problems, are mixed feeding at hospital discharge and less likely to breastfeed through 6 months.

This study aims to compare the effect of two massage programs of an electric massage chair to evaluate if they work on to hasten the onset of lactation (lactogenesis stage II).

Who can participate?
First time mothers aged 18-45 years, without any serious illness or chronic disease, with a straightforward vaginal delivery, a healthy baby and planning to breastfeed.

What does the study involve?
Participants will be randomised into 2 groups:
(1) The intervention group will be given a back massage program using the electric massage chair twice daily, for 20 minutes each session, starting from 3-6 hours postdelivery, until the day of discharge.
Or
(2) The control group will be given a calf massage program using the electric massage chair twice

daily, for 20 minutes each session, starting from 3-6 hours postdelivery, until the day of discharge.
Follow up for 10 days post-delivery.

What are the possible benefits and risks of participating?
The allocated massage may hasten, have no effect or delay onset of lactation. The massages may increase relaxation or cause discomfort. Use of massage chair is not expected to cause major adverse consequences.

Where is the study run from?
University of Malaya Medical Centre (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
January 2024 to December 2024

Who funds this study?
The Department of Obstetrics & Gynaecology, UMMC (Malaysia)

Who is the main contact person?
Dr Nurul Atiqah Binti Radzali, atiqah.radzali@ummc.edu.my
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
MREC ID NO: 2023713-12663

Study information

Scientific Title
Mechanical Massage By An Electric Massage Chair on Lactogenesis Stage II (Onset of Lactation) In First-Time Mothers: A Randomised Controlled Trial

Study objectives
Mechanical back massage will hasten the onset of lactation (lactogenesis stage II) in first-time mothers after a vaginal delivery

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/02/2024, Medical Research Ethics Committee University Of Malaya Medical Centre (Lembah Pantai , Kuala Lumpur, Kuala Lumpur, 59100, Malaysia; +60 03-79493209; ummc-mrec@ummc.edu.my), ref: MREC ID NO: 2023713-12663

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Efficacy

Health condition(s) or problem(s) studied
Onset of lactation in first time mothers

Interventions
Participants after written informed consenting will be randomised into two groups:
1. The intervention group will be given a back massage program using the electric massage chair twice daily, for 20 minutes each session, starting from 3-6 hours postdelivery, until the day of discharge.
Or
2. The control group will be given a calf massage program using the electric massage chair twice daily, for 20 minutes each session, starting from 3-6 hours postdelivery, until the day of discharge.

Randomisation sequence will be generated separately using an online generator (https://www.sealedenvelope.com/simple-randomiser/v1/lists), in 1 to 1 ratio and random blocks of 4 or 8, by a co-investigator who will not be involved in the recruitment process. Randomisation will be implemented using strict sequential assignment of the lowest-numbered remaining sealed envelope to the newest recruit.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mechanical Electric Massage Chair

Primary outcome(s)
1. Time from birth to onset of lactation (lactogenesis stage II) [As reported by the mother on daily assessment]
Breast fullness is rated on a 5-point scale: from 1 (no change) to 3 (noticeably full) to 5 (uncomfortably full). Onset of lactation is defined as the first breast fullness score of 3 or greater as reported by the mother.

Key secondary outcome(s))
1. Maternal satisfaction with their assigned mechanical massage chair experience using a 11 point (0-10) numerical rating scale prior to discharge. [As reported by the mother]
2. Baby's breastfeeding performance using Infant Breastfeeding Assessment Tool (IBFAT) prior to discharge. [As reported by the mother]
3. Baby's breastfeeding performance using Infant Breastfeeding Assessment Tool (IBFAT) at Day 10 after birth. [As reported by the mother]
4. Exclusive breastfeeding at Day 10 after birth. [As reported by the mother]
IBFAT score of 10–12 indicates successful breastfeeding, a score of 7–9 relatively successful breastfeeding and a score of 0–6 unsuccessful breastfeeding.

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Primiparous
2. Spontaneous vaginal deliveries mother without complications
3. 18 - 45 years
4. Singleton pregnancy
5. Term pregnancy > 37 weeks
6. Birth weight > 2500g
7. No serious illness/chronic disease
8. Ability to read and write, acceptable ability of listening and speaking to answer the questions
9. Intention to breastfeed
10. Can communicate in Malay or English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria
1. Contraindication to breastfeeding
2. Postpartum complication e.g., haemorrhage, chorioamnionitis, retained placenta, any invasive procedures and blood transfusion
3. Newborns with complications

Date of first enrolment
01/04/2024

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
University Of 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
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

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 Dr Nurul Atiqah Radzali (atiqah.radzali@ummc.edu.my)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	22/10/2023	19/02/2024	No	Yes
Participant information sheet	version 2.0	24/02/2024	27/02/2024	No	Yes
Protocol file	version 1	22/10/2023	19/02/2024	No	No
Protocol file	version 2.0	24/02/2024	27/02/2024	No	No