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High blood pressure in pregnancy: the effect of mechanical massage with electrical massage chair on reducing blood pressure

Submission date
12/02/2025

Recruitment status
No longer recruiting

Registration date
12/02/2025

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
High blood pressure disorder during in pregnancy (HDP) account for about 14% of all maternal deaths worldwide with 18.1 million new cases of HDP estimated to occur in 2019. HDP is a leading cause of the death of babies including stillbirths, malformations in babies, poor baby growth during pregnancy, very low birth weight and very premature birth. Current management strategies for HDP focus on blood pressure control using medications and timely delivery. Manual massage by hand can lower blood pressure in the short term. In non-pregnant populations, a 15-minute moderate pressure chair massage session results in unconscious changes to the nervous system toward a setting favouring the lowering of blood pressure during the massage. The immediate effect of mechanical massage using an automated electric massage chair to lower blood pressure in pregnancies affected by high blood pressure is not known. This study plans to evaluate if a 30-minute massage session of the back portion of the head, neck, shoulders, torso, buttocks and limbs using the electric massage chair compared to just sitting comfortably on the massage chair without the massage function activated for 30 minutes can lower blood pressure in the 4-hours immediately after the session in hospitalised pregnant women with high blood pressure in addition to the best of standard care high blood pressure treatment.

Who can participate?
Hospitalised adult women of 20 weeks pregnant with high blood pressure who are not anticipated to need delivery within the next 24 hours.

What does the study involve?
All participants are expected to spend two 30-minute session on the electric massage chair. The sessions will be 4 hours apart.
In one group, the session will start with the massage function activated followed 4 hours later by a second session when the massage function will be inactivated. In the other group, the order is reversed; first session massage function inactivated, and second session massage function activated. Group assignment of participants will be performed by computer.
Immediately before, and immediately, 1, 2, and 4 hours after each session the participants blood

pressure and pulse will be measured using an automated blood pressure monitor. In the 4 hours between the chair sessions, participants will receive standard care and allowed the usual ward activities. Standard clinical care always applies.

What are the possible benefits and risks of participating?
Mechanical massage by the electric chair may temporarily lower blood pressure demonstrating its potential for use an additional treatment method for high blood pressure in pregnancy. For this short-term study, no major benefit is anticipated.
The mechanical massage may be perceived to be uncomfortable and this discomfort may cause your blood pressure to temporarily increase. Participants are instructed that they can change the massage setting or to stop the massage at any time and for any reason. For this short-term study, no major harm is anticipated.

Where is the study run from?
The Department of Obstetrics & Gynaecology, Universiti Malaya.

When is the study starting and how long is it expected to run for?
September 2024 to December 2025

Who is funding the study?
The Department of Obstetrics & Gynaecology, Universiti Malaya.

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Mechanical massage with an electrical massage chair on blood pressure in hypertensive disorders in pregnancy: a randomised counterbalanced cross-over trial

Study objectives
Mechanical massage with an electric massage chair rapidly reduces blood pressure in hypertensive disorder in pregnancy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/09/2024, University of Malaya Medical Centre Medical Research Ethics Committee (University Malaya Medical Center, Lembah Pantai, 59100, Malaysia; +60 379498473; ummcmrec@ummc.edu.my), ref: 2024715-13920

Study design
Randomized counterbalanced crossover placebo-controlled

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Hypertensive disorder in pregnancy

Interventions
Randomisation will be conducted by opening a numbered, sealed, opaque envelope, with the lowest numbered envelope available assigned to the latest recruit. The randomization sequence will be generated in random blocks of 4 or 8 (1:1 ratio) using https://www.sealedenvelope.com /simple-randomiser/v1/lists by a co-investigator who will not be involved in trial recruitment.

Participants will be allocated to one of two trial arms:
Arm 1: ON-MASSAGE followed by OFF-MASSAGE after a 6-hour gap
OR
Arm 2: OFF-MASSAGE followed by ON-MASSAGE after a 6-hour gap.

Massage Chair Intervention (ON-MASSAGE): Participants will receive a session of automated mechanical massage on the massage chair (involving the neck, posterior shoulders, and back). The intervention will consist of a 30-minute massage session delivered once only. Participants will have the option to adjust the massage intensity according to their preference and select the massage chair's incline for their comfort. During the session, participants will be seated comfortably on the massage chair, and the massage program will be initiated. Participants will vacate the massage chair after the 30-minute session and return to their usual inpatient activity. The massage program can be terminated at any time by a participant by pressing a button on the control panel – this activity will be shown to participants and their understanding will be actively demonstrated before starting the massage session. Blood pressure and heart rate measurements will be taken before the session, immediately after the session, and at 1-, 2-, and

4-hours post-session.
Control Intervention (OFF-MASSAGE): Participants will sit on the massage chair without activating the massage function. They will spend 30 minutes on the chair but will not receive any massage therapy as a 'placebo' control, similarly, delivered once only. Participants will have the option to select the massage chair's incline for their comfort. During the session, participants will be seated comfortably on the massage chair, but no active massage program will be initiated. Participants will vacate the massage chair after the 30-minute session and return to their usual inpatient activity. Blood pressure and heart rate measurements will be taken before the session, immediately after the session, and at 1-, 2-, and 4-hours post-session.

The sequence of interventions will be counterbalanced by one-to-one randomisation, with one arm starting with ON-MASSAGE followed by OFF-MASSAGE, while the other arm will begin with OFF-MASSAGE followed by ON-MASSAGE. There will be a 6-hour interval between the sessions for washout, to reduce any immediate or very short-term carry-over effects from the first session.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electric massage chairs (automated)

Primary outcome(s)
Immediate systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial blood pressure (MAP - calculated using the formula MAP = DBP + 1/3[SBP – DBP]) values and change, measured using an automated blood pressure machine at the end of the ON or OFF sessions for each participant

Key secondary outcome(s))
1. SBP, DBP, MAP, and HR are measured using an automated blood pressure machine at 1, 2, and 4 hours after each massage chair session
2. Maternal satisfaction is measured using a 0-10 numerical rating scale immediately after completion of each session
3. Change to anti-hypertensive medications is measured using patient records within the next 24 hours
4. Eclampsia observed within 6 hours of massage chair session
5. Clinical placental abruption observed within 6 hours of massage chair session

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Admission to antenatal ward
2. Diagnosis of hypertensive disorder in pregnancy: prior systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥90 mmHg on at least 2 occasions, at least 4 hours apart during pregnancy

3. Gestational age ≥20 weeks
4. Age ≥18 years
5. Able to consent

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 massage therapy
2. Severe complications necessitating immediate medical intervention (e.g. imminent delivery, hypertensive crisis, magnesium sulphate therapy)

Date of first enrolment
17/02/2025

Date of final enrolment
17/08/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Lembah Pantai
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Center

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Obstetric and Gynaecology Department of University Malaya Medical Center

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Tan Peng Chiong, pctan@um.edu.my subject to institutional review board approval

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		10/05/2024	12/02/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes