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Compression stockings to reduce the risk of low blood pressure during epidural pain relief in labour: a randomised study

Submission date
18/01/2026

Recruitment status
Recruiting

Registration date
21/01/2026

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Many women choose an epidural to help with pain during labour. While epidurals are very effective, they can sometimes cause a drop in blood pressure, especially soon after the epidural is started. Low blood pressure can make women feel unwell with symptoms like nausea, dizziness, or a racing heart, and in some cases it can affect the baby. This happens because epidurals relax blood vessels, and because the weight of the pregnant uterus can slow the return of blood from the legs to the heart when a woman lies on her back. Compression stockings gently squeeze the legs and may help blood flow back to the heart more easily. They are cheap, simple, and do not involve drugs, but it is not yet clear whether they really reduce the risk of low blood pressure during labour epidurals. This study aims to find out whether wearing compression stockings before and during an epidural reduces the chance of low blood pressure in labour.

Who can participate?
Pregnant women who are at least 37 weeks pregnant, are admitted to hospital for a planned vaginal birth, and choose or need an epidural for pain relief during labour may be able to take part.

What does the study involve? (for participants)
Women who may be eligible are first checked against the study criteria. Those who are eligible are given written information about the study and have the chance to ask questions before deciding whether to take part. Women who agree to participate sign a consent form. Their leg measurements are then taken to decide the right size of compression stockings. Women whose leg size is larger than the available study stocking sizes cannot take part. Participants are then randomly assigned, by chance, to receive either correctly sized compression stockings or stockings that are deliberately looser. Neither the participant nor the clinical team choosing the treatment knows which type has been assigned. If the woman later goes on to have an epidural, the allocated stockings are put on within 30 minutes before the epidural is given. Blood pressure

is measured regularly before and after the epidural, following normal hospital practice. The study team records blood pressure readings and whether the stockings were worn as planned. No extra procedures beyond standard care and the stockings themselves are required.

What are the possible benefits and risks of participating?
Taking part may reduce the chance of low blood pressure during and after the epidural, which could also reduce discomfort such as nausea, dizziness, or palpitations. Compression stockings may also help lower the risk of blood clots in the legs. The risks are low, but some women may experience discomfort, skin irritation, or bruising from the stockings, particularly if they feel tight or are not worn properly.

Where is the study run from?
University Malaya Medical Centre in Malaysia.

When is the study starting and how long is it expected to run for?
The study is expected to start in February 2026 and run until December 2026.

Who is funding the study?
University Malaya Medical Centre in Malaysia.

Who is the main contact?
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Study information

Scientific Title
Compression stockings for epidural analgesia in labour on maternal hypotension: A blinded randomised sham-control trial

Acronym
TED-LAB

Study objectives
To evaluate the effectiveness of compression stockings during epidural analgesia in labour to prevent maternal hypotension

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/11/2025, Medical Research Ethics Committee University of Malaya Medical Centre (University of Malaya Medical Centre) (LEMBAH PANTAI, KUALA LUMPUR, 59100, Malaysia; +60 3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2025724-15392

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Prevention of hypotension following labour epidural analgesia in pregnant women admitted at term for planned vaginal delivery

Interventions
All participants will receive standard care for labour and epidural analgesia as per hospital protocol, including intravenous fluid preload, continuous monitoring, and epidural administration by an anaesthetist.

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

Participants will be randomised to:
A) Stockings of the appropriate size as active intervention
Or
B) Stockings three sizes larger than their measured appropriate size (or the largest size available if three sizes larger is not available: the largest available size is 3XL, participants measured at 3XL or beyond are excluded from the study before randomisation) to serve as blinded sham control.

Trial stockings as randomly allocated will be applied within 30 minutes before siting of the labour epidural. The standard application technique for anti-embolic stockings for our centre will be used.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medi-Ortho medical-grade thrombo-embolism deterrent (TED) stockings, providing a graduated compression level of 18 mmHg at the ankle composed of 80% nylon and 20% spandex, The product is MDA registered in Malaysia (Registration No. GA9204122-82878).

Primary outcome(s)

1. Maternal hypotension in the first 60 minutes after epidural analgesia (Hypotension is defined as the occurrence of at least one of the following:1) >20% drop in systolic blood pressure from baseline 2) >20%drop in diastolic blood pressure from baseline 3) >20% drop in mean arterial blood pressure from baseline 4) Systolic blood pressure < 90 mmHg) measured using electronic medical records at within the first 60 minutes following the administration of labour epidural analgesia.

Key secondary outcome(s)

1. Late Maternal Hypotension, defined as at least one occasion of: >20% drop in systolic, diastolic, or mean arterial blood pressure from baseline, or systolic blood pressure < 90 mmHg measured using electronic medical records at from 60 minutes post-epidural administration until delivery

2. Early requirement for vasopressors and doses used measured using recorded presence and total cumulative dose of vasopressor drugs retrieved from electronic medical records at within the first 60 minutes after epidural administration

3. Late requirement for vasopressors and doses used measured using recorded presence and total cumulative dose of vasopressor drugs retrieved from electronic medical records at beyond 60 minutes of epidural up to delivery

4. Presence of maternal symptoms measured using "Yes" or "No" responses on direct questioning regarding nausea, dizziness, vomiting, or palpitations at after 60 minutes of epidural administration

5. Fetal heart rate abnormality: Tachycardia (defined as a fetal heart rate ≥ 160 bpm for at least 15 minutes) measured using electronic medical records at within 60 minutes of epidural administration

6. Fetal heart rate abnormality: Decelerations (Defined as 15 bpm below baseline for at least 15 seconds on at least two occasions) measured using electronic medical records at within 60 minutes of epidural administration

7. Fetal heart rate abnormality: Bradycardia (Defined as a fetal heart rate < 100 bpm for at least 60 seconds) measured using electronic medical records at within 60 minutes of epidural administration

8. Early clinical diagnosis of non-reassuring fetal status measured using electronic fetal monitoring records at within 60 minutes of epidural administration

9. Clinical diagnosis of non-reassuring fetal status up to delivery measured using electronic medical records at at delivery

10. Epidural administration to delivery interval measured using time duration (in minutes or hours) recorded from electronic records at at delivery

11. Estimated delivery blood loss measured using measured or estimated blood loss (ml) retrieved from electronic medical records at at delivery

12. Mode of delivery measured using recording of delivery type: spontaneous vaginal, instrumental, or caesarean section retrieved from medical records at at delivery

13. Indications for operative delivery measured using recording of indications for operative delivery retrieved from medical records at at delivery

14. Patient satisfaction with the wearing of compression stockings measured using 0–10 numerical rating scale at prior to hospital discharge

15. Neonatal APGAR scores measured using retrieved from electronic records at at 1 and 5 minutes after delivery

16. Umbilical cord artery blood pH measured using retrieved from medical records at immediately following delivery

17. Neonatal intensive care unit (NICU) admissions and indications measured using retrieved from medical records at during the immediate postpartum period

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Admitted for vaginal delivery
2. Singleton pregnancies
3. Term gestation (≥ 37 weeks)
4. Compression stocking size ≤2XL
5. Requesting or requiring epidural anaesthesia for labour pain management
6. Baseline blood pressure immediately before epidural ≥ 90/60 mmHg and considered suitable for epidural

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria

1. Known severe hypertension in pregnancy (BP ≥ 160/110 mmHg)
2. Known contraindication to epidural analgesia
3. Known cardiovascular conditions
4. Contraindications to stocking use (e.g. skin reaction, allergy to material, open wound, local infection)

Date of first enrolment
01/03/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Malaysia

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University of Malaya Medical Centre (UMMC)
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Petaling Jaya
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Sponsor information

Organisation
Department of Obstetrics and Gynaecology, University of Malaya

Funder(s)

Funder type

Funder Name
Department of Obstetrics and Gynaecology, University of Malaya

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 Dr. Nur Farhah Najwa Binti Ayub (farhahnajwa92@gmail.com) and/or Dr. Wong Thai Ying (thai.wong@um.edu.my) and subject to our institutional review board

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	CASE REPORT FORM		19/01/2026	No	No
Other files	ELIGIBILITY ASSESSMENT FORM [EAF]		19/01/2026	No	No
Participant information sheet			19/01/2026	No	Yes
Protocol file			19/01/2026	No	No