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Operative vaginal delivery accompanied by a birth companion

Submission date 03/05/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/05/2024	**Overall study status** Completed	
Last Edited 07/05/2024	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Operative vaginal birth, also called instrumental vaginal birth, refers to a vaginal birth using instruments (e.g., a vacuum device or forceps) to deliver the baby's head. It is performed for a variety of reasons including a quick delivery of a compromised baby, exhaustion of the mother with pushing, pushing effort that has taken too long, and in circumstances where pushing is inadvisable on medical grounds.
Labour companions provide emotional, practical and informational support, bridging communication with clinical staff, helping women to feel in control and confident by giving praise and reassurance and acting as advocates for the women. In addition, labour companions increase the chance of normal vaginal birth, shorten the duration of labour, decrease the use of painkillers and epidurals in labour, and decrease negative feelings about childbirth experiences. Many healthcare professionals seem reluctant to let the partner be present during emergency caesarean sections, whereas mothers and partners seem to prefer it. In this centre, the standard practice is to request the patient’s birth companion to leave the labour room for the duration of an operative vaginal delivery.
Women, partners, and healthcare providers view information, positive interaction and communication with providers, and respectful care as facilitators for acceptance of operative vaginal delivery and barriers include lack of training and skills, for decision-making and use of instruments.
The aim of this study is to find out whether the continued presence of a birth companion in the delivery room at an operative vaginal delivery improves the birth experience satisfaction of women, plausibly of their birth companions, without negatively impacting the surgeons’ experience or care.

Who can participate?
Women aged 18 years and over at term with a birth companion in their labour who need an operative vaginal delivery for the usual medical reasons

What does the study involve?
Participants will be randomly allocated to one of two groups:
1. Their birth companion stays in the delivery room at the top of the bed to provide support through the operative vaginal delivery

OR
2. The birth companion leaves the delivery room for the duration of the delivery (standard practice)

What are the possible benefits and risks of participating?
The presence of a birth companion at operative vaginal birth may improve the patients' and their companions' satisfaction with the conduct of the birth. The presence of a birth companion in a centre where a birth companion is usually asked to leave the delivery room at operative vaginal birth may be perceived to disrupt the conduct of the delivery and lead to less satisfaction all around.

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 June 2025

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
1. Dr Nur Hamizah Binti Mohamad, hamizah.m@ummc.edu.my
2. Prof. Dr Tan Peng Chiong, pctan@um.edu.my
3. Dr Farah Binti Mohd Faiz Gan, farah.faizg@ummc.edu.my

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Nur Hamizah Binti Mohamad

Contact details
University Malaya Medical Centre,
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)12-5195020
hamizah.m@ummc.edu.my

Type(s)
Scientific

Contact name
Dr Farah binti Mohd Faiz Gan

Contact details
University Malaya Medical Centre
Lembah Pantai

Kuala Lumpur
Malaysia
59100
+60 (0)176345907
farah.faizg@ummc.edu.my

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2024126-13310

Study information

Scientific Title
Operative vaginal delivery with a birth companion: a randomized control trial

Study objectives
An operative vaginal delivery conducted with a birth companion present compared to no birth companion present will:
1. Increase maternal and companion satisfaction with the operative delivery (superiority hypothesis)
2. Not decrease surgeon experience of the operative delivery (non-inferiority hypothesis)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/03/2024, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 (0)3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2024126-13310

Study design
Single-centre parallel-design randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Operative vaginal delivery

Interventions
Patients in early labour will be screened for their eligibility to participate. Potentially eligible patients will be approached, provided with the patient information sheet, and verbally engaged on trial aspects by the care provider for trial participation. Informed written consent will be

obtained from all participants. The final inclusion criteria is the requirement for operative vaginal delivery.

The randomisation sequence will be generated using the online site https://www.sealedenvelope.com by an investigator not involved in trial recruitment. Numbered, sealed and opaque envelopes containing the randomly allocated trial intervention will be prepared. The lowest number envelope available will be opened for the latest recruit to reveal their allocated trial intervention. Inappropriately opened envelopes will be discarded and the event recorded.

Participants will be randomised to:
1. The birth companion is to remain in the delivery room, staying at the top of the bed with the patient to provide support through the operative vaginal delivery
OR
2. The birth companion is to leave the delivery room for the duration of the operative vaginal delivery (standard practice)

Intervention Type
Other

Primary outcome(s)
Satisfaction with the operative vaginal birth experience, scored using the 0-10 numerical rating scale [NRS], a low score indicating less satisfaction within 24 hours of delivery, by the:
1. Participant
2. Birth companion
3. Surgeon-care provider
Recorded at a single timepoint right after delivery

Key secondary outcome(s))
Recorded at a single timepoint right after delivery:
1. Time it takes to deliver (insertion of the instrument to delivery of the baby as recorded in the medical record)
2. Mode of delivery (as recorded in the medical record)
3. Change of instrument for operative delivery (as recorded in the medical record)
4. Perineal injury sustained (as recorded in the medical record)
5. Estimated delivery blood loss (as recorded in the medical record)
6. Perineal pain on movement on Day 1 measured with a 0-10 NRS (obtained the day following delivery)
7. Neonatal outcomes:
7.1. Apgar score at 1 and 5 minutes (as recorded in the medical record)
7.2. Umbilical cord artery pH and base excess (as recorded in the medical record)
7.3. Neonatal injury (as recorded in the medical record)
7.4. Neonatal admission and indication (as recorded in the medical record)
7.5. Time to first satisfactory breastfeeding episode (maternally self-defined, time and date recorded as soon as soon as reported)

Completion date
30/06/2025

Eligibility

Key inclusion criteria

1. A birth companion was already present during the labour
2. Birth companion willing to be present at operative vaginal delivery if so randomised
3. Singleton pregnancy
4. Term gestation >36 weeks
5. Age ≥18 years
6. Able to communicate in Malay or English
7. Final inclusion criteria: Women who required operative vaginal delivery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Breech presentation
2. Intrauterine death
3. Participants who refused to be accompanied by their birth companions for operative vaginal delivery
4. Major fetal anomaly

Date of first enrolment
01/06/2024

Date of final enrolment
30/06/2025

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
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

Funder Name
Investigator initiated and funded

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 Nur Hasimah (xxxx@siswa.um.edu.my) subject to institutional review board approval

IPD sharing plan summary
Available on request