

Serial Membrane Sweeping at term in planned Vaginal Birth After Caesarean

Submission date 12/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 13/05/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/11/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
601.12

Study information

Scientific Title

Serial weekly membrane sweeping at term in women who planned vaginal birth after one caesarean delivery: a randomised trial

Acronym

SMS_VBAC Trial

Study objectives

That serial weekly stretching of the cervix and stripping of the membrane from the lower segment of the uterus at term will facilitate the onset of spontaneous labour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Malaya Medical Centre Medical Ethics Committee gave approval on the 25th July 2007 (ref: 601.12)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Planned vaginal birth after caesarean

Interventions

Weekly cervical stretching and membrane stripping (membrane sweeping) from greater than 36 weeks gestation versus weekly gentle vaginal examination (control).

Random allocation to membrane sweeping or gentle vaginal examination. Allocated treatment conducted as an outpatient procedure in the antenatal clinic. The treatment continues on a weekly basis until delivery has occurred. Standard management of pregnancy and delivery applies.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Spontaneous labour, defined as:

1. Regular painful contractions that had resulted in at least 3 cm of cervical dilation, or
2. Confirmed pre-labour rupture of membranes

Key secondary outcome(s)

1. Caesarean delivery
2. Formal labour induction
3. Recruitment to delivery interval
4. Gestational age at delivery
5. Number of membrane sweep or control sessions conducted
6. Bishop score at each session
7. Unscheduled hospitalisation
8. Significant antepartum haemorrhage
9. Prostaglandin and oxytocin use
10. Duration of hospitalisation at birth
11. Epidural analgesia
12. Neonatal outcomes of umbilical artery blood pH, Apgar score at 5 minutes and birth weight

All obtained by the time of discharge from hospital after birth, i.e., no later than 6 weeks after enrolment.

Completion date

06/11/2008

Eligibility

Key inclusion criteria

Pregnant women with the following characteristics:

1. One previous transverse lower segment caesarean scar
2. Singleton pregnancy
3. Foetus in cephalic presentation
4. Intact membranes
5. Gestational age greater than 36 week
6. Agreed to a trial of vaginal birth
7. Passed physician screening for a trial of vaginal birth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Otherwise eligible women with the following are excluded:

1. Placenta praevia
2. Suspected foetal macrosomia
3. Suspected cephalopelvic disproportion
4. Abnormal foetal lie
5. Obstructive pelvic masses

Date of first enrolment

07/09/2007

Date of final enrolment

06/11/2008

Locations

Countries of recruitment

Malaysia

Study participating centre

Department of Obstetrics and Gynaecology

Kuala Lumpur

Malaysia

50603

Sponsor information

Organisation

University of Malaya (Malaysia)

ROR

<https://ror.org/00rzspn62>

Funder(s)

Funder type

University/education

Funder Name

University of Malaya (Malaysia)

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009		Yes	No