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Serial Membrane Sweeping at term in planned Vaginal Birth After Caesarean

Submission date	Recruitment status	[_] Prospectively registered
12/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/11/2009	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 pegnancy and delivery applies.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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

Secondary outcome measures
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.

Overall study start date
07/09/2007

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

Age group

Adult

Sex
Female

Target number of participants
At least 211

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)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type

University/education

Website
http://www.um.edu.my/

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, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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