

# Serial Membrane Sweeping at term in planned Vaginal Birth After Caesarean

<b>Submission date</b> 12/05/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/11/2009	<b>Condition category</b> 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)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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?
<a href="#">Results article</a>	results	01/10/2009		Yes	No