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

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

#### Plain English summary of protocol

Not provided at time of registration

### Contact information

#### Type(s)

Scientific

#### Contact name

Prof Peng Chiong Tan

#### Contact details

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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 pegnancy 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)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

# **Study outputs**

Output type	Details	Date created Date	e added Peer review	ed? Patient-facing?
Results article	results	01/10/2009	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/1	11/2025 No	Yes