

# Abdominal application of talcum powder or aqueous gel to aid external cephalic version

<b>Submission date</b> 23/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

During pregnancy, babies often twist and turn. By the time labour begins, most babies settle into a position that allows them to be born headfirst through the birth canal. That doesn't always happen, though. If the baby is lying feet first with their bottom downwards, they are in the breech position. This makes care more complicated. Patients are usually offered the option of an external cephalic version (ECV). This is when an obstetrician tries to turn the baby into a head-down position by applying pressure on the mother's abdomen. The aim of this study is to test whether applying talcum powder or gel to the mother's abdomen improves the success rate of ECV.

### Who can participate?

Women from 36 weeks of pregnancy onwards with a baby in the breech position who are about to undergo ECV

### What does the study involve?

Participants are randomly allocated to have either talcum powder or gel applied during ECV. ECV is performed in the standard way and participants receive standard antenatal care. The success rate of ECV and participants' satisfaction with the procedure are measured. If ECV fails and the baby stays in the breech position, then the participant undergoes Caesarean delivery at 38–39 weeks of pregnancy.

### What are the possible benefits and risks of participating?

The results of this study will help guide the choice of lubricant for ECV. There are no possible risks for the patient on participating in this study.

### Where is the study run from?

University Malaya Medical Centre (UMMC) (Malaysia)

### When is the study starting and how long is it expected to run for?

January 2011 to December 2012

Who is funding the study?  
University Malaya (Malaysia)

Who is the main contact?  
1. Dr Vallikkannu Narayanan  
2. Prof. Tan Peng Chiong

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Vallikkannu Narayanan

**Contact details**  
University Malaya  
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41100

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
MEC Ref: No: 818.5

## Study information

**Scientific Title**  
Powder vs gel for external cephalic version: a randomised trial

**Study objectives**  
Is abdominal application of talcum powder better than aqueous gel for external cephalic version.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Medical Ethics Committee University Malaya Medical Centre, 20/10/2010, ref: 818.5

**Study design**

Randomised 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**

Clinical obstetrics: in the management of breech presentations

**Interventions**

Abdominal application of talcum powder versus aqueous gel to aid in performing external cephalic version

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Current primary outcome measures as of 03/01/2013:

1. Procedure satisfaction score by Visual Numerical Rating Scale (VNRS)
2. Success rate of external cephalic version

Previous primary outcome measures until 03/01/2013:

1. Procedure pain score by Visual Numerical Rating Scale (VNRS)
2. Success rate of external cephalic version

**Secondary outcome measures**

1. Provider's satisfaction with powder or gel using VNRS.
2. Post ECV CTG anomalies
3. Cephalic presentation at Birth
4. Caesarean delivery rate
5. Neonatal Outcome (SCN admission, Apgar score, cord pH)
6. Mode of delivery

**Overall study start date**

01/01/2011

**Completion date**

01/12/2012

## Eligibility

**Key inclusion criteria**

1. Women from 36 weeks and beyond about to undergo external cephalic version
2. Viable Singleton with breech presentation
3. Gestation  $\geq$  36 weeks ( check for early confirmation of Gestational Age)
4. Intact membranes
5. Not in established labour ( contractions and cervix  $\leq$  3cm dilated)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

80

**Key exclusion criteria**

1. Known gross fetal anomaly
2. Severe hypertension ( $\geq$  160/110 mmHg or confirmed per-eclampsia)
3. IUGR ( EFW  $<$  2 kg or US AC  $<$  10th centile on our chart)
4. Oligohydramnios ( AFI  $<$ 5)
5. Antepartum haemorrhage within last seven days.
6. Uterine scar from any source
7. Known Allergy to powder or gel
8. Other potential obstetric indication for caesarean delivery
- 8.1. Placenta praevia
- 8.2. Suspected macrosomia  $>$ 4 kg
- 8.3. Uterine anomaly (small fibroids not causing obstruction are acceptable)
- 8.4. Obstructive pelvic tumour

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

01/12/2012

## Locations

**Countries of recruitment**

Malaysia

**Study participating centre**  
**University Malaya**  
Klang  
Malaysia  
41100

## **Sponsor information**

**Organisation**  
University Malaya (Malaysia)

**Sponsor details**  
Institut Pengurusan dan Pemantauan Penyelidikan  
Blok C, Aras 3, Bangunan Institut Pengajian Siswazah (IPS)  
Kuala Lumpur  
Malaysia  
50603

**Sponsor type**  
University/education

**Website**  
<http://www.ippp.um.edu.my>

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

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University Malaya (Malaysia) ref: RG370/11 HTM

## **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?
<a href="#">Results article</a>	results	28/01/2014		Yes	No