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

Submission date
23/11/2012

Recruitment status
No longer recruiting

Registration date
11/12/2012

Overall study status
Completed

Last Edited
13/09/2016

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
34, Lorong Pokok Sakat
41100, Klang,
Selangor
Klang
Malaysia
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 ≥ 36 weeks (check for early confirmation of Gestational Age)
4. Intact membranes
5. Not in established labour (contractions and cervix ≤ 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 (≥ 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?
Results article	results	28/01/2014		Yes	No