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Terbutaline tocolysis for external cephalic version: a randomised comparison of the 250 µg versus 500 µg bolus dose

Submission date	Recruitment status	[ ] Prospectively registered
09/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/05/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/05/2009	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peng Chiong Tan

Contact details
Department of Obstetrics and Gynaecology
Faculty of Medicine
University of Malaya
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Additional identifiers

Protocol serial number
672.21

Study information

Scientific Title

A double-blind randomised trial of 250 µg versus 500 µg bolus dose of terbutaline as a tocolytic agent in external cephalic version

Acronym
TORSION STUDY

Study objectives
A larger terbutaline dose will provide more effective tocolysis resulting in a higher rate of successful external cephalic version.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Centre Medical Ethics Committee gave approval on the 27th August 2008 (ref: 672.21)

Primary study design
Interventional

Study design
Double blind randomised trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breech presentation at term

Interventions
Women are randomised to 250 µg or 500 µg of bolus subcutaneous terbutaline followed by external cephalic version 15 minutes later with a maximum of two attempts.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Terbutaline

Primary outcome(s)
1. Immediate success rate of external cephalic version (ECV)
2. Caesarean delivery rate
3. Cephalic presentation at birth

All determined by no later than at the birth of the baby.

Key secondary outcome(s)

1. Post-ECV cardiotocograph abnormalities
2. Neonatal outcomes:
2.1. Neonatal nursery admission
2.2. Apgar score at 5 minutes
2.3. Umbilical cord arterial blood, pH
3. Adverse drug events
4. Visual Analog Scale (VAS) satisfaction score with ECV
5. Indication for operative delivery

Determined by no later than hospital discharge following birth.

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Non-cephalic presentation
2. Singleton pregnancy
3. Gestation greater than or equal to 36 weeks (check for early confirmation of gestational age)
4. Intact membranes
5. Reassuring foetal status on cardiotocograph

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Known gross foetal anomaly
2. Severe hypertension (greater than or equal to 160/110 mmHg or confirmed pre-eclampsia)
3. Growth restricted foetus (estimated foetal weight less than 2 kg or ultrasound-derived foetal abdominal circumference less than 10 centile on our chart)
4. Oligohydramnios (amniotic fluid index [AFI] less than 5)
5. Antepartum haemorrhage within last 7 days
6. Uterine scar from any source
7. Known allergy to terbutaline
8. Other potential obstetric indication for caesarean delivery:
8.1. Placenta praevia
8.2. Suspected macrosomia greater than 4 kg
8.3. Uterine anomaly (small fibroids not causing obstruction are acceptable)
8.4. Obstructive pelvic tumour

Date of first enrolment

27/08/2008

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Malaysia

Study participating centre
Department of Obstetrics and Gynaecology
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya Medical Centre (Malaysia)

ROR
https://ror.org/00vkrxq08

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