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

	Recruitment status	Prospectively registered
09/05/2009 N	No longer recruiting	<pre>Protocol</pre>
Registration date C	Overall study status	Statistical analysis plan
13/05/2009 C	Completed	Results
Last Edited C	Condition category	Individual participant data
	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

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# 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)

#### Study design

Double blind randomised trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Breech presentation at term

#### **Interventions**

Women are randomised to 250  $\mu$ g or 500  $\mu$ g 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** 

#### Kev 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

# 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)

# **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?

Participant information sheet Participant information sheet 11/11/2025 No Yes