ISRCTN14802064 https://doi.org/10.1186/ISRCTN14802064

# External Cephalic Version (ECV) Tocolysis Trial: Oral nifedipine vs subcutaneous terbutaline

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 15/07/2008 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 31/07/2008 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 31/07/2008 | Pregnancy and Childbirth | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
459.5

## Study information

**Scientific Title**
Oral nifepidine versus subcutaneous terbutaline tocolysis for external cephalic version: A double blind randomised trial

## Acronym
STONE Trial

## Study objectives
Oral nifedipine is comparable to subcutaneous terbutaline as tocolysis for external cephalic version

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
University of Malaya Medical Centre, Medical Ethics Committee. Date of approval: 17/08/2005 (ref: 459.5)

## Primary study design
Interventional

## Study design
Randomised, double-blind trial

## Study type(s)
Prevention

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

## Interventions
Participants were randomised to treatment with 10 milligram oral nifedipine tablet and subcutaneous saline placebo injection or oral placebo tablet and subcutaneous 250 microgram terbutaline injection administered 20-30 minutes before commencing external cephalic version.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
1. Successful version to cephalic presentation
2. Caesarean delivery

## Key secondary outcome(s)
1. Cephalic presentation at birth
2. Post-ECV cardiotocographic anomalies
3. Visual analogue scale satisfaction score with ECV procedure
4. Onset of labour
5. Neonatal outcome
6. Survey on patient preference of oral vs injection mode of medication

7. Maternal peri-delivery blood loss
8. Indication for operative delivery
9. Adverse drug events

### Completion date
01/12/2007

## Eligibility

### Key inclusion criteria
1. Breech presentation or transverse lie
2. Viable, singleton pregnancy
3. Gestation age 36 to 41 weeks
4. Intact membranes
5. Not in established labour

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
1. Known gross foetal anomaly
2. Severe hypertension
3. Intrauterine growth restriction
4. Oligohydramnios
5. Antepartum haemorrhage within last 3 months
6. Uterine scar from any source
7. Known allergy to nifedipine or terbutaline
8. Other potential obstetric indication for Caesarean delivery
8.1. Placenta praevia
8.2. Suspected macrosomia >4 kg
8.3. Uterine anomaly
8.4. Obstructive pelvic tumour

### Date of first enrolment
01/12/2005

### Date of final enrolment
01/12/2007

## Locations

**Countries of recruitment**
Malaysia

**Study participating centre**
**Department of Obstetrics & 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, Department of Obstetrics and Gynaecology (Malaysia)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration