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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)

Study design
Randomised, double-blind trial

Primary study design
Interventional

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