ISRCTN22145023 https://doi.org/10.1186/ISRCTN22145023

Single Injection 17-hydroxyprogesterone caproate in Preterm labour: a randomised controlled trial

Submission date	Recruitment status	[X] Prospectively registered
22/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/02/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2014	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
516.4

Study information

Scientific Title

Acronym
SIP

Study objectives
17-hydroxyprogesterone caproate in conjunction with standard tocolysis may increase the latency period in preterm labour.

Please note that as of 24/06/2008 more details on the sources of funding have been added to this record (i.e., funding now confirmed). This can be seen below in the sources of funding section.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Centre Medical Ethics Committee, 19/07/2006

Study design
Randomised double-blind placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm labour

Interventions
Single injection of 250 mg of 17-hydroxyprogesterone acetate versus placebo saline injection.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
17-hydroxyprogesterone caproate

Primary outcome(s)
1. Delivery within 48 hours
2. Delivery within seven days

Key secondary outcome(s))
1. Delivery before 34 weeks
2. Delivery before 37 weeks
3. Mode delivery
4. Birth weight

5. Gestational age at delivery
6. Apgar score (five minute)
7. Umbilical cord blood pH at birth
8. Admission to the neonatal unit
9. Perinatal mortality
10. Neonatal morbidity including Respiratory Distress Syndrome (RDS), IntraVentricular Haemorrhage (IVH), Necrotising EnteroColitis (NEC), surfactant use, mechanical ventilation

Completion date
15/02/2009

Eligibility

Key inclusion criteria
1. Suspected preterm labour (based on presence of contractions and/or cervical changes)
2. 22 to 35 weeks gestation
3. Scheduled for standard tocolysis and prophylactic antenatal corticosteroids

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Multiple gestations
2. Foetal death
3. Membrane rupture
4. Maternal pyrexia more than 38°C
5. Indications for immediate delivery

Date of first enrolment
15/02/2007

Date of final enrolment
15/02/2009

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) (ref: PJP/F0174/2007B)

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

Funder Name
CCM Duopharma Malaysia Biotech Berhad (Malaysia) - supply of trial medication

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary