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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
1. Delivery within 48 hours
2. Delivery within seven days

Secondary outcome measures
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

Overall study start date
15/02/2007

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

Age group
Adult

Sex
Female

Target number of participants
256

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)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor type
University/education

Website
http://www.ummc.edu.my

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, 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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration