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17-Alpha hydroxyprogesterone in Multiple pregnancies to Prevent Handicapped InfAnts

Submission date 02/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/01/2007	**Overall study status** Completed	
Last Edited 06/09/2011	**Condition category** Pregnancy and Childbirth	

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
N/A

Study information

Scientific Title

Acronym

AMPHIA

Study objectives
Prophylactic administration of 17-alpha HydroxyProgesterone Caproate (17OHPC) will reduce the incidence of the composite neonatal morbidity of neonates by reducing the early preterm birth rate in multiple pregnancies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (MEC AMC Amsterdam) on November 30th 2005, (reference number: 05/102).

Study design
Randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Multiple pregnancy

Interventions
Participants will receive weekly intramuscular injections of 17OHPC or placebo, starting at a gestational age between 16 and 20 weeks and continuing until 36 weeks. Cervical length will be measured at time of randomisation.

Further pregnancy and labour management will be according to local protocol.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
17-alpha HydroxyProgesterone Caproate

Primary outcome(s)
The primary outcome will be composite neonatal morbidity, containing severe Respiratory Distress Syndrome (RDS), BronchoPulmonal Dysplasia (BPD), intraventricular haemorrhage stage IIB or worse, Necrotising EnteroColitis (NEC), proven sepsis and death before discharge.

Key secondary outcome(s))
Secondary outcome measures are:
1. Time to delivery
2. Preterm birth rate before 32 and 37 weeks

3. Days of admission in neonatal intensive care unit
4. Maternal morbidity
5. Maternal admission days for preterm labour
6. Costs

Completion date
01/02/2009

Eligibility

Key inclusion criteria
1. Women with a multiple pregnancy
2. Gestational age between 15 and 19 weeks
3. Aged 18 and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Major congenital anomaly of (one of) the fetuses
2. Death of (one of) the fetuses
3. Early signs of Twin-to-Twin Transfusion Syndrome
4. Primary cerclage
5. Previous preterm birth less than 34 weeks

Date of first enrolment
01/08/2006

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Lundlaan 6
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands) (ref: subsidy 62200019)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No
Protocol article	protocol	19/06/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes