

17-Alpha hydroxyprogesterone in Multiple pregnancies to Prevent Handicapped Infants

Submission date 02/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.studies-obsgyn.nl/amphia>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/08/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

700

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)

Sponsor details

PO Box 93245

Den Haag

Netherlands

2509 AE

Sponsor type

Research organisation

Website

<http://www.zonmw.nl>

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

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

Study outputs

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