

# 17-Alpha hydroxyprogesterone in Multiple pregnancies to Prevent Handicapped Infants

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

**Contact name**  
Prof HW Bruinse

**Contact details**  
Lundlaan 6  
P.O.Box 85090  
Utrecht  
Netherlands  
3508 AB  
+31 (0)30 2504000  
[H.W.Bruinse@umcutrecht.nl](mailto:H.W.Bruinse@umcutrecht.nl)

## 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?
<a href="#">Protocol article</a>	protocol	19/06/2007		Yes	No
<a href="#">Results article</a>	results	01/09/2011		Yes	No