# Costs and effects of amniotomy at home for induction of post-term pregnancy

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
09/01/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/01/2006	Completed	Results
Last Edited	Condition category	Individual participant data
13/06/2014	Pregnancy and Childbirth	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

Type(s)

Scientific

#### Contact name

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#### Contact details

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#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** NTR504

# Study information

#### Scientific Title

Costs and effects of amniotomy at home for induction of post-term pregnancy in low-risk women: a pragmatic randomised controlled trial

#### Acronym

**SERINAM** 

#### **Study objectives**

We hypothesise that in low-risk women amniotomy at home for post-term pregnancy will result in more spontaneous birth (defined as labour and birth without any obstetric intervention but amniotomy) resulting in lower costs during birth.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from the local medical ethics committee

#### Study design

Multicentre randomised active-controlled parallel-group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### Health condition(s) or problem(s) studied

Pregnancy, post-term pregnancy

#### Interventions

If referral for post-term pregnancy is planned within the next 24 hours, randomisation takes place:

- 1. The intervention group will receive amniotomy at home and expectant management of labour for 12 hours
- 2. The control group will be referred to an obstetrician at 294 days and receives usual standard care

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

- 1. Percentage of women that will deliver without obstetric interventions besides amniotomy
- 2. Data of pregnancy outcome, performed management and obstetric interventions are obtained from midwives and obstetricians with a CRF designed for this study
- 3. Data regarding patient expectations of birth and birth management are obtained from participating women by questionnaire. This will take place in pregnancy between 292-294 days but before randomisation.
- 4. Data about patient satisfaction and patient costs are obtained by questionnaire within 1 month postpartum

#### Secondary outcome measures

- 1. Proportion caesarean section and admission to the neonatal intensive care unit (NICU)
- 2. Other obstetric interventions on maternal or foetal indication, pain relief, maternal and foetal morbidity, medical and patient costs, patient satisfaction

#### Overall study start date

01/10/2004

#### Completion date

01/10/2007

### Eligibility

#### Key inclusion criteria

- 1. Informed consent
- 2. Women with a single foetus in cephalic position
- 3. Pregnancy of 292 days or more
- 4. Receiving prenatal care from a midwife in a freestanding midwifery practice

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Female

#### Target number of participants

500

#### Key exclusion criteria

- 1. A history of neonatal infection
- 2. A history of endometritis
- 3. A history of stillbirth
- 4. A positive GBS culture
- 5. A suboptimal foetal condition

- 6. Contractions
- 7. Rupture of membranes
- 8. Communication problems

#### Date of first enrolment

01/10/2004

#### Date of final enrolment

01/10/2007

#### Locations

#### Countries of recruitment

Netherlands

# Study participating centre TNO Quality of life

Leiden Netherlands 2301 CE

# Sponsor information

#### Organisation

Midwifery Academy Amsterdam (The Netherlands)

#### Sponsor details

Louwesweg 6 Amsterdam Netherlands 1066 EC +31 (0)20 5124231 kvjry@slz.nl

#### Sponsor type

Not defined

#### **ROR**

https://ror.org/02nt7ap43

# Funder(s)

#### Funder type

#### Funder Name

Not provided at time of registration

## **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