ISRCTN47736435 https://doi.org/10.1186/ISRCTN47736435

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

Submission date 09/01/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/01/2006	**Overall study status** Completed	
Last Edited 13/06/2014	**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

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
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Sponsor type
Not defined

ROR
https://ror.org/02nt7ap43

Funder(s)

Funder type

Not defined

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