

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

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

**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**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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)

**ROR**  
<https://ror.org/02nt7ap43>

## **Funder(s)**

**Funder type**  
Not defined

**Funder Name**  
Not provided at time of registration

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration