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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21694

Bron
Nationaal Trial Register

Verkorte titel
SERINAM

Aandoening

Post term pregnancy defined as a pregnancy of 294 days or more occurs in approximately 6% of all pregnancies and is associated with an increased risk for neonatal morbidity and a small but significant increased risk of neonatal mortality.

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

In the Dutch obstetric system a distinction is made between low-risk and high-risk birth. Low risk births are attended by a primary care caregiver (midwife or G.P.) and take place either at home, in a freestanding birth clinic or in hospital.
High- risk deliveries are defined as the presence of conditions which place the woman or baby at risk during birth and take place in hospital attended by a secondary care caregiver (obstetrician).
The distinction in low, medium or high risk is based on national guidelines for obstetric care. About 35% of all deliveries are cared for by a midwife, and 30% of all babies are born at home.

Post term pregnancy (defined as 294 days or more) is associated with perinatal complications and therefore a reason for referral to an obstetrician.

To prevent women to become high risk and thus referred to an obstetrician, amniotomy could be done at home between 292 and 294 days thus trying to induce labour at home.
This might be preferable for women and gives them a last chance to have a “normal” (home) birth.

A RCT in 34 midwifery practices in the Netherlands is set up to estimate the costs and effects of amniotomy at home followed by expectant management of labour compared to usual care for low risk post-term women.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

The intervention group will receive amniotomy at home and expectant managment of labour for 12 hours.

The the control group will be refferred to an obstetrician at 294 days and receives usual standard care.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

After informed consent women with a single fetus in cephalic position and a pregnancy of 292 days or more, receiving prenatal care from a midwife in a freestanding midwifery practice are included in the trial.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are a history of neonatal infection, endometritis, stillbirth, and in this pregnancy a positive GBS culture, a suboptimal fetal condition, contractions, rupture of membranes or communication problems.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2004
Aantal proefpersonen:	500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL463
NTR-old	NTR504
Ander register	: N/A
ISRCTN	ISRCTN47736435

Resultaten

Samenvatting resultaten
N/A