Indicated amniotomy in the latent phase of labour

Published: 16-04-2009
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To judge if there is a difference between referral rates during labour when an amniotomy is performed in the latent phase of labour, compared to an expectant policy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Maternal complications of labour and delivery
Study type	Interventional

Summary

ID

NL-OMON33760

Source
ToetsingOnline

Brief title
Amniotomy

Condition

- Maternal complications of labour and delivery

Synonym
progress failure

Research involving
Human

Sponsors and support

Primary sponsor: Verloskunde Academie Rotterdam
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: amniotomy, labour, nulliparae, progress failure

Outcome measures

Primary outcome

Referral rate during labour

Secondary outcome

Rate of instrumental deliveries (including Ceasarean section)

duration of first stage of labour

duration of second stage of labour

Study description

Background summary

Midwives in the Netherlands are referring more and more labouring women to secondary care, due to progress failure of the first stage. But the moment when labour is not progressing normally anymore, is not well defined. As a reaction on this, the Royal Dutch Organisation for Midwives (KNOV) produced a guideline: "progress failure of the first stage". More or less at the same time a book named: "Preventive Support of Labour" was published, written by the obstetricians Reuwer en Bruinse. Recommendations in the book and the guideline differ substantially from each other, specially in the timing of the moment of performing an amniotomy. The effect of an indicated amniotomy in the latent phase of labour is to our best knowledge not studied before.

Study objective

To judge if there is a difference between referral rates during labour when an amniotomy is performed in the latent phase of labour, compared to an expectant policy.

Study design

Randomized controlled trial (pilot)

Intervention

amniotomy

Study burden and risks

To our best known: none. (Both policies are being practiced, without evidence of the benefits)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

nulliparae
term pregnancy
singleton
cephalic presentation
spontaneous labour, latent phase

intact membranes

Exclusion criteria

floating head

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL21547.078.08