The use of foley catheter results in less interventions as compared to the use of propess

Published: 08-01-2009
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To objective the most efficacy way to ripening the cervix of pregnant women.

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

Summary

ID

NL-OMON32840

Source
ToetsingOnline

Brief title
FLIC

Condition

- Maternal complications of labour and delivery

Synonym
ripening/priming

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: foley and propess

Outcome measures

Primary outcome

percentage of caesarean sectio

Secondary outcome

- bishop 6 or higher after treatment

- neonatale outcome

- fever

- the amount of syntocinon

- total gifts of propess

- time to delivery

- total costs

- anesthesia

Study description

Background summary

Ripening the uterine cervix is an intervention that must be done for about 5% of the pregnant women. There are two options to do.
First by way of intravaginal prostaglandine. Studies show that there is a higher chance on fetal distress because of hyperstimulation for which reason a caesarean sectio is indicated.
The second option is to use a Foley catheter an inexpensive method. There is a lower chance of hyperstimulation and therefore also on caesarean sectio.
Even we like to investigate if there is a higher chance of infection by using a foley catheter, which has never been investigated.

Study objective

To objective the most efficacy way to ripening the cervix of pregnant women.

Study design

A randomised trial.

Intervention

At the moment there is a indication for induction they get the information letter.
With help of the randomisation procedure they will get into the group of propess of into the group of the Foley catheter.

Study burden and risks

no extra risk for the patient.

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

single pregnancy at term who has a bishop score lower than 6

Exclusion criteria

broken membranes/who have had a sectio/bad foetal condition

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2009
Enrollment:	194
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	propess
Generic name:	dinoproston

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2008-007931-41-NL
CCMO	NL25524.042.08