INDEX:Costs and effects of induction of labour versus expectant management in women with impending post-term pregnancies: the 41 week-42 week dilemma

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First ObjectiveIn this study we compare a policy of labour induction at 41 weeks with a policy of expectant management until 42 weeks, with an outpatient check for CTG monitoring and ultrasound measurement in the 42nd week, with respect to the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON41657

Source
ToetsingOnline

Brief title
INDEX

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
postterm pregnancy, prolonged pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cost-effectiveness Analysis, induced labor, prolonged pregnancy

Outcome measures

Primary outcome

perinatal mortality and neonatal morbidity

Adverse perinatal outcomes are defined as a 5-minute Apgar-score below 7 and/or

an arterial pH below 7.05

meconium aspiration syndrome

plexus brachialis injury

intracranial hemorrhager

NICU admission.

Secondary outcome

instrumental delivery (instrumental vaginal delivery, Caesarean section)

pain treatment (epidural, remifentanyl, pethidin)

hemorrhage and severe perineal injury (third- or fourth-degree perineal tear)

maternal experience of pain

maternal satisfaction and quality of life

client preferences for induction of labour or expectant management and the

extent to which these preferences are influenced by the attributes of obstetric

care and socio-demographic factors.

Study description

Background summary

Post-term pregnancy is associated with increased perinatal morbidity and mortality and is considered as a high-risk stage which requires specialist surveillance and induction of labour at some stage. However, there is uncertainty in The Netherlands on the policy concerning the timing of induction for post-term pregnancy, leading to practice variation and strong debates between caregivers regarding pros and cons of labour induction for impending post-term pregnancy. To solve this dilemma in the Netherlands we propose a randomised trial to evaluate the effectiveness, costs and cost-effectiveness analysis of policy of labour induction at 41 weeks versus expectant management until 42 weeks in low risk women. We will study adverse perinatal outcome, adverse maternal outcomes, client satisfaction, preferences and costs.

Study objective

First Objective
In this study we compare a policy of labour induction at 41 weeks with a policy of expectant management until 42 weeks, with an outpatient check for CTG monitoring and ultrasound measurement in the 42nd week, with respect to the adverse perinatal outcome rate.

Secondary Objective(s):
Based on the data obtained, we will perform a cost-effectiveness analysis incorporating instrumental delivery rates, client satisfaction and costs.

We will analyse costs of both strategies, as well as clients* preferences, pain, anxiety and maternal satisfaction.

We will answer the following specific questions:
What is in a policy of induction of labour at 41 weeks as compared to a policy of expectant management until 42 weeks
* Maternal satisfaction
* The instrumental delivery rate including Caesarean sections
* Need for pain relieve
* Perineal injury
* Post partum hemorrhage
* Use of health care resources
* Clients* preferences

Study design

The study is a multi-centre randomised clinical trial with a cost-effectiveness

analysis and a preference study alongside it.

Intervention

Induction of labour according to local protocol.

Study burden and risks

Participants fill out questionnaires at five occasions; at four occasions this will take them about 15 minutes, the fifth questionnaire will take less than 5 minutes to be answered. Although formally induction of labour is only indicated at 42 weeks gestational age, at many hospitals it is actual practice to induce at 41 weeks GA. This study therefore compares two common treatment strategies as a result of which it will not impose extra risk on the participants.

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

- Low risk pregnancy
- Singleton pregnancy
- Gestational age between 40+5 weeks until 41+2 weeks
- Reliable dating based on first trimester ultrasound
- Stable cephalic position
- Patients of 18yrs or older

Exclusion criteria

* Ruptured Membranes
* Other obstetrical indications for secondary care
* Proteinuria .3 g/L or more
* Renal disease
* Heart disease
* Fetal abnormalities including abnormal karyotype.
* Uncertain estimates of gestational age
* No consent for immediate delivery

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2012
Enrollment:	1800
Type:	Actual

Ethics review

Approved WMO Date:	27-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-11-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-09-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Not approved Date:	07-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL38455.018.11