The Eindhoven Breech Intervention Study (EBIS)

Published: 15-03-2007
Last updated: 20-06-2024

Primary outcome is to evaluate whether successful ECV is associated with maternal thyroid function and mood state in single pregnant women with breech position at end term.

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

Summary

ID

NL-OMON30624

Source
ToetsingOnline

Brief title
Ebis

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
External version of a foetus in breech position

Research involving
Human

Sponsors and support

Primary sponsor: Maatschap gynaecologie Catharina-ziekenhuis
Source(s) of monetary or material Support: Aanvraag bij industrie en wetenschappelijk fonds Catharina-ziekenhuis wordt gedaan.,Ferring

Intervention

Keyword: Breech Presentation, External Cephalic Version, Thyroid funcion tests

Outcome measures

Primary outcome

Main study parameters/endpoints: Main study parameter is the difference in mean FT4 (thyroid hormone) in women with successful ECV compared to those with no successful outcome of ECV. Moreover the independent relation between maternal mood state versus successful ECV will be assessed.

Secondary outcome

A secondary outcome is to evaluate whether neonatal thyroid parameters is associated with ECV.

Study description

Background summary

Maternal hypothyroxinemia during gestation is associated with impaired motor development of the offspring. Foetal movements is generally accepted to be important to present the foetus at term in cephalic position. Breech position is associated with increased foetal and maternal morbidity which means that low risk interventions that can reduce breech position may reduce this increased risk. External cephalic version (ECV) is a low risk intervention which - if successful - reduces the risk of Caesarean Section up to 80%. Until now, ECV is successfully performed in 40 - 50% of the cases.
Parity, type of breech presentation, localisation of the placenta and birthweight are important determinants of succes.
So far no biochemical determinants are known.

Study objective

Primary outcome is to evaluate whether successful ECV is associated with maternal thyroid function and mood state in single pregnant women with breech position at end term.

Study design

Prospective observational study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is no burden and risk associated with participation: women are only asked to participate into EBIS after they decided to have ECV as part of routine good clinical practice. Assessment of blood samples also do not include additional invasive research: all women already have a vena-punction as a parameter of the safety protocol for routine ECV in clinical practice. Neonatal thyroid parameters will be assessed in cord blood after the dissection of the placenta from the umbilical cord.

Intervention (if applicable): No additional intervention is applicable except for several questionnaires to assess maternal mood state.

Contacts

Public
Maatschap gynaecologie Catharina-ziekenhuis

Michelangelolaan 2
6523 EJ Eindhoven
Nederland
Scientific
Maatschap gynaecologie Catharina-ziekenhuis

Michelangelolaan 2
6523 EJ Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Single pregnancy
-Gestation of 35 weeks or more
-Appropriate knowledge of the Dutch language
-Foetus in any of the 4 types of breech presentation:
• Frank breech presentation (highest incidence)
• Complete breech presentation (nonfrank breech presentation)
• Incomplete breech presentation
• Footling presentation

Exclusion criteria

• Indications for caesarean delivery irrespective of presentation (eg, placenta previa)
• Previous caesarean section
• Previous abruptio placenta
• Multiple pregnancy
• Ruptured membranes
• Nonreassuring fetal monitoring test results
• Hyperextended fetal head
• Significant fetal or uterine anomaly
• Use of thyroid medication
• Maternal autoimmune diseases such as insulin-dependent diabetes mellitus or rheumatoid arthritis
• Intra-uterine growth retardation
• Oligo or anhydramnion
• Hiv-positive women

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2007
Enrollment:	208
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL14584.060.06