Implementation of the external cephalic version in breech delivery.
Dutch national implementation study of external cephalic version.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22365

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Implementation of external cephalic version in obstetric care in The Netherlands.

Sponsors and support

Primary sponsor: Prof. dr. BW Mol
Academic Medical Center
dept. obstetrics & gynaecology,
Room H4-213
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Primary endpoint is the number of patients that has an ECV performed.

Secondary outcome

Secondary endpoints are guidelines' adherence rates, complications at ECV, the number of children that is in cephalic position at delivery, the number of caesarean sections and the perinatal condition of mother and child. Moreover, we will assess patient knowledge (e.g. ECV, breech delivery, caesarean section), patient decisional conflict and patient satisfaction. We will also calculate costs of both implementation interventions and medical interventions. In case one or both implementation interventions are effective, their cost-effectiveness will be assessed.

Study description

Background summary

Breech presentation occurs in 3 to 4 % of all term pregnancies. External cephalic version (ECV) is proven effective to prevent vaginal breech deliveries and therefore it is recommended by clinical guidelines of the The Royal Dutch Organisation for Midwives (KNOV) and The Dutch Society for Obstetrics and Gynaecology (NVOG). Implementation of ECV does not exceed 50 to 60% and probably less.

The aim of this study is to assess barriers and facilitators of implementation of ECV in The Netherlands, and to develop an innovative implementation strategy based on improved patient counselling and information of health care providers as cornerstones.

The ultimate purpose of this implementation study is to improve counselling of pregnant women and information of clinicians to realize a better implementation of ECV.
The first fase of the project is to detect the barriers and facilitators of ECV. The next step is to develop an implementation strategy to:

1. Inform and counsel pregnant women with a breech presentation;

2. Inform and education of the care providers.

In the third fase, the effectiveness of the developed implementation strategy will be

evaluated in a randomised trial. The study population is a random selection of midwives and gynaecologists from 60 to 100 hospitals and practices.

Secondary endpoints are process indicators, the amount of children in cephalic presentation at birth, complications due to ECV, the number of caesarean sections and perinatal condition of mother and child. Cost effectiveness of the implementation strategy will be measured.

Study objective

The aim of this study is to assess barriers and facilitators of implementation of external cephalic version in The Netherlands, and to develop an innovative implementation strategy based on improved patient counselling and information of health care providers as cornerstones.

Study design

The first fase will be completed at the end 0f 2009 and results will be reported to Zon MW. After permission, the second and third fase will be accomplished.

Intervention

In the first two phases of the study, a omplementation plan will be developed. The regions of the participating hospitals will be randomized either to the control group, or to the group starting to work with the implementation plan.

Contacts

Public
Academic Medical Center (AMC)
Dept Gynaecology & Obstetrics, H4-140.1
Meibergdreef 8

F. Vlemmix
Academic Medical Center (AMC)
Dept Gynaecology & Obstetrics, H4-140.1
Meibergdreef 8

Amsterdam 1105AZ
The Netherlands
+31-(0)20-5666199
Scientific
Academic Medical Center (AMC)
Dept Gynaecology & Obstetrics, H4-140.1
Meibergdreef 8

F. Vlemmix
Academic Medical Center (AMC)
Dept Gynaecology & Obstetrics, H4-140.1
Meibergdreef 8

Amsterdam 1105AZ
The Netherlands
+31-(0)20-5666199

Eligibility criteria

Inclusion criteria

The proposal will contain three phases. In the first phase, we will identify facilitators and barriers of implementation of ECV. Subsequently, we will develop an implementation strategy targeted on patient counselling and information of health care providers, and evaluate the cost-effectiveness of the developed strategy.

All hopsitals in midwife practices in The Netherlands are potential candidates for the randomized controlled trial of the implementation developes model.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1768
NTR-old	NTR1878
Other	ZonMW : 80-82315-98-09011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A