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

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22365

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Prof. dr. BW Mol
Academic Medical Center
dept. obstetrics & gynaecology,
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1105 AZ Amsterdam
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Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2009

Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1768
NTR-old	NTR1878
Ander register	ZonMW : 80-82315-98-09011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A