Continuous Care Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27156

Source
Nationaal Trial Register

Brief title
Continue Trial (CCT)

Health condition

Vaginal birth

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMw projectnummer: 209070001

Intervention

Outcome measures

Primary outcome

Usage of epidural analgesia during labor

Secondary outcome

referral from primary care tot secondary care, percentage caesareans, percentage instrumental deliveries, adverse outcomes from epidural (in general fever, augmentation of labor, prolonged labor, postpartum hemorrhage, hospitalization of mother and/or newborn),

cost-effectiveness, budget impact analysis and patient satisfaction.

Study description

Background summary

Background
To improve perinatal outcome, in 2009 the Steering Committee for Pregnancy and Childbirth in the Netherlands advised to implement continuous care during labor, although clear data on cost effectiveness are lacking. Despite a marked rise in the use of epidural anesthesia, current obstetrical caregivers are not able to supply continuous care for more than 70% of women. In the Dutch system, maternity care assistants supply care during the last stages of labor and the question is whether to extent care to a longer period of time would be a cost effective intervention.
Methods
We propose an RCT on continuous care compared to care as usual. All multiparous and nulliparous women with an intention to a vaginal delivery, with understanding of the Dutch language and > 18 years of age can be included. The intervention consist of continuous care by a trained maternity assistant (MA) from the moment the obstetrical caregiver states labor has started.
The primary outcome will be use of epidural analgesia. Secondary outcomes are mode of delivery, complications, patient satisfaction and cost effectiveness which will be calculated by QALY per prevented EA based on utility index from the EQ-5D and usage of healthcare. Standardized sensitivity analysis will be done to quantify the outcome and a budget impact analysis will be done . In order to show a reduction from 25% to 17% in the primary outcome 2x496 women are needed

Study objective

Continuous care during labor by a maternity care assistant will reduce the usage of an epidural and will reduce complications and is therefore costeffective and increases patient satisfaction about their labor experience

Study design

Inclusion started 30-08-2018

Intervention

Continuous support during labor from the moment midwife states labor has started by a maternity care assistant

Contacts

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Eligibility criteria

Inclusion criteria

Planned vaginal birth
Women from 18 years or older
Pregnancy in third trimester
Living in the region of south Limburg

Exclusion criteria

Planned caesarean
Not able to read informed consent (knowledge of Dutch language)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-08-2018
Enrollment:	992
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	03-10-2019
Application type:	First submission

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	NL8065
CCMO	NL51853.068.17

Study results