Continuous Care Trial

Gepubliceerd: 03-10-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27156

Bron
Nationaal Trial Register

Verkorte titel
Continue Trial (CCT)

Aandoening

Vaginal birth

Ondersteuning

Primaire sponsor: ZonMW
Overige ondersteuning: ZonMw projectnummer: 209070001

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Usage of epidural analgesia during labor

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

Inclusion started 30-08-2018

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Maastricht University
Adrie Lettink

0031642510292

Wetenschappelijk

Maastricht University
Adrie Lettink

0031642510292

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	30-08-2018
Aantal proefpersonen:	992
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	03-10-2019
Soort:	Eerste indiening

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	NL8065
CCMO	NL51853.068.17

Resultaten