Continious Care trial: The effect of continuous care during childbirth given by a maternity care nurse.

Published: 27-06-2018
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The effect of continuous care during childbirth care compared with current standard care, in which continuous guidance has not yet been achieved.

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

Summary

ID

NL-OMON55455

Source
ToetsingOnline

Brief title
CC trial

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
Epidural anesthesia, patient satisfactory

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: continious care, epidural anesthesia, labor

Outcome measures

Primary outcome

Percentage of epidural anesthesia

Secondary outcome

Secondary outcomes include shift of care from outpatient care by midwife to inpatient care by doctor of clinical midwife, percent sectio caesarea, vacuum and forceps deliveries.

We also want to evaluate cost-effectiveness, adverse outcome index, budget impact analysis and patient and healthcare satisfaction

Study description

Background summary

The advice of 'de stuurgroep zwangerschap en geboorte' to provide continuous care during childbirth has not been sufficiently implemented at this momen. In the outpatient care by midwifes, this is currently around 20% in the Limburg region and in the inpatient care in hospitals this is realized in about 35% of cases. Midwives and doctors are insufficient to take on this task, and maternity nurses seem to be a good choice. However, the (cost) effectiveness of more guidance by maternity care nurses during childbirth should first be investigated.

Study objective

The effect of continuous care during childbirth care compared with current standard care, in which continuous guidance has not yet been achieved.

Study design

Multicenter, non-blinded, randomised controlled trial

Intervention

Continuous care and support of the pregnant woman by a maternity nurse during birth(intervention group) versus regular supervision by midwife or doctor (control group).

Study burden and risks

no extra risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- pregnancy in third trimester
- Living in Provence of Limburg
- planning to deliver bij spontaans birth

Exclusion criteria

- scheduled sectio cesare
- Unable to understand or read informed consent
- <18 years f age

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2018
Enrollment:	1017
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-02-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL61853.068.17