

Cost-effectiveness of two strategies to implement the NVOG guidelines on hypertension in pregnancy: An innovative strategy including a computerised decision support system compared to a common strategy of professional audit and feedback

No registrations found.

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

Summary

ID

NL-OMON28902

Source

Nationaal Trial Register

Brief title

BIG (BOS on implemaentation of guidelines)

Health condition

Pre-eclampsia
Pregnancy
Gestational hypertension
Implementation
Guidelines
Computerized decision support system
Cost-effectiveness

Implementatie, richtlijnen, pre-eclampsie, pre-existente hypertensie, zwangerschap, zwanherschaphypertensie

Sponsors and support

Primary sponsor: ZonMw

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measure for the evaluation of the effectiveness of both strategies is a combined rate of major maternal complications (maternal death, organ specific complications of hypertension, HELLP syndrome, placental abruption)

Secondary outcome

- Guidelines' adherence rates
- Fetal death rates
- Caesarean delivery rates
- Rates of neonatal mortality and morbidity
- Experiences with the implementation strategies. (participation etc)

Study description

Background summary

The objective of this study is to assess the cost-effectiveness of an innovative implementation strategy of the NVOG guidelines of hypertension including a computerised decision support system compared to a common strategy of professional audit and feedback

Study objective

N/A

Study design

- 8 months preparation

- 24 months implementation study and follow-up
- 4 months analysis and report

Intervention

Implementation strategy, BOS (beslissings ondersteunend systeem) versus audit and feedback.

Contacts

Public

VU University Medical Center

Department of Obstetrics and Gynaecology
8F-013

Postbus 1117
S.H.E. Luitjes
Amsterdam 1007 MB
The Netherlands
+31 (0)6 20837607

Scientific

VU University Medical Center

Department of Obstetrics and Gynaecology
8F-013

Postbus 1117
S.H.E. Luitjes
Amsterdam 1007 MB
The Netherlands
+31 (0)6 20837607

Eligibility criteria

Inclusion criteria

1. Pregnant women who develop severe hypertension or preeclampsia

Exclusion criteria

1. Refusal to participate

2. Diagnosis of lethal fetal congenital abnormalities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion	
Date:	15-07-2008
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	NL1327
NTR-old	NTR1387
Other	170883003 : 222
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A