Temporise or Terminate pregnancy in women with severe preeclampsia at 28-34 weeks.

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To investigate the hypothesis that temporising treatment of women with early-onset, severe preeclampsia improves infant outcome and may reduce direct treatment costs in comparison to short-term planned delivery, while persistent maternal morbidity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON39398

Source
ToetsingOnline

Brief title
TOTEM

Condition

- Maternal complications of pregnancy

Synonym
gestational hypertension, toxicosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: preeclampsia, pregnancy, temporisation, termination

Outcome measures

Primary outcome

The primary outcome is composite major neonatal morbidity and perinatal mortality.

Secondary outcome

The secondary long-term neonatal outcome is a Bailey assessment at two years corrected age. The secondary short-term maternal outcome is the occurrence of major complications before and after delivery. The secondary long-term maternal outcome is persistent morbidity or death. Cost analysis calculates direct health care costs of mother and infant until discharge.

Study description

Background summary

During pregnancy hypertensive disorders are a frequent cause of maternal morbidity and mortality and an important cause of neonatal morbidity and mortality. The only effective treatment is termination of pregnancy, but at an early gestational age this is questionable since temporising management and prolongation of the pregnancy may possibly improve neonatal outcome. Present obstetric knowledge is not sufficient to decide how to balance between the risks of maternal complications and the benefits of the neonate.

Study objective

To investigate the hypothesis that temporising treatment of women with early-onset, severe preeclampsia improves infant outcome and may reduce direct treatment costs in comparison to short-term planned delivery, while persistent maternal morbidity or death are comparable.

Study design

After admission for severe preeclampsia patients will be stabilised with antihypertensive medication and magnesium sulphate and administered corticosteroids for inducement of fetal maturity according to standard practice. After 24 hours, patients, who did not develop a major maternal complication after admission or a fetal indication for delivery, will be randomised for either termination of pregnancy 48 hours after admission or for expectant management. Randomisation will be stratified for gestational age lower or higher than 31 weeks and for participating centre.

Intervention

Temporising of pregnancy starting 24 hours after randomisation. Pregnancy will only be terminated when maternal and/or fetal complications occur or when the gestational age of 34 weeks is reached.

Study burden and risks

At least the short-term health risks for the mother in the temporising schedule seem to be acceptable in the clinical setting of a level III center. The direct burden may be a longer stay in hospital, but this is customary until now. The possible neonatal risks are unknown, but may be related to the degree of prematurity, especially when delivered at an earlier stage. However, in preeclamptic pregnancies the benefits of prolonging pregnancy may be counteracted by the dangers of the underlying maternal disease. Also in case of prolonging these pregnancies the length of prolonging is relatively short.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Informed consent
Working knowledge of Dutch language
Gestational age 27.6 - 33.5 weeks at inclusion
Estimated fetal weight >= 500 gram at inclusion
No major fetal congenital anomalies
Severe preeclampsia (modified from the criteria for severe preeclampsia (ACOG practice bulletin no. 33, table 1))

Exclusion criteria

Therapy resistant hypertension
Severe maternal complications
Fetal indication for immediate delivery
Major fetal congenital anomalies or estimated fetal weight below 500 grams

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2011
Enrollment:	1130
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Not approved Date:	09-09-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-06-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL21849.078.08