Pregnancy related Acute hyperTension Intervention Action: a randomized trial comparing labetalol and nicardipine in women with acute hypertension in pregnancy (Platina-trial)

Published: 26-03-2018
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OBJECTIVE: To compare, in women with acute severe hypertensive disorders, clinical effectiveness of labetalol and nifedipine.

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

Summary

ID

NL-OMON47595

Source
ToetsingOnline

Brief title
Platina-trial

Condition

- Maternal complications of pregnancy

Synonym
hypertension in pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hypertension, labetalol, nicardipine, pregnancy

Outcome measures

Primary outcome

PRIMARY OUTCOME MEASURES: Composite poor maternal and neonatal outcome

(mortality and morbidity).

POWER/DATA ANALYSIS: Analysis will be intention-to-treat. To detect a

difference of 15% in neonatal and maternal outcome with 90% power and alpha

0.05 we will include 472 women (236 per arm).

Secondary outcome

Maternal morbidity and mortality

Study description

Background summary

Approximately 10% of pregnancies are complicated by hypertensive disorders (roughly 19 000 women yearly in The Netherlands). Approximately one third of hypertensive disorders are severe and contribute substantially to maternal and neonatal morbidity and mortality (iatrogenic preterm delivery).

RATIONALE: Evidence on which antihypertensive is most effective in treating severe hypertensive disorders is lacking resulting in suboptimal care due to lack of uniform policy and under-treatment.

Study objective

OBJECTIVE: To compare, in women with acute severe hypertensive disorders, clinical effectiveness of labetalol and nifedipine.

Study design

APPROACH: Randomized Controlled Trial with an economic analysis.

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Intervention

INTERVENTIONS: Intravenous administration of labetalol iv vs. oral nifedipine

Study burden and risks

Hypertension in pregnancy occurs in 10% of pregnancies (roughly 190 000 women per year in the Netherlands) and is usually mild in the majority of women. However, about 1 in 3 of these women (60 000 women per year) develops severe hypertension that puts them at high risk for maternal and neonatal morbidity and mortality, and therefore justifies immediate treatment. Until women have delivered their baby, with or without a period of intended prolongation of pregnancy, adequate blood pressure control is of paramount importance.
There is consensus that women should receive antihypertensive drugs to lower their blood pressure, but, in absence of clear evidence, it is unclear which antihypertensive drug is preferred. The lack of evidence on this subject reflects in considerable practice variation. As in other parts of the world, in the Netherlands labetalol, nicardipine, nifedipine, ketanserin, hydralazine and combinations of these medications are used. In view of the potentially relevant differences for both mother and neonate between these medications, there is an urgent need for insight in the optimal treatment of women with severe hypertension in pregnancy. Such insight will allow a rational standard leading to uniformity in treatment that could improve patient safety and maternal and neonatal outcome and quality of life.
Uniform treatment of severe hypertension in pregnancy will result in improvement of maternal and neonatal outcome with a reduction of admission to maternal and neonatal intensive care. Although severe maternal complications, including eclamptic seizures, cerebral hemorrhage, HELLP syndrome, liver hematoma and rupture, pulmonary edema and maternal death are rare even in women with hypertension, the high prevalence of hypertension in pregnancy itself, makes that many young women and their neonates/children are affected, both in the Netherlands and worldwide.
Evidence to support the choice of an antihypertensive is lacking. A Cochrane review on the subject concluded, *until better evidence is available, the choice of antihypertensive should depend on the clinician's experience and familiarity with a particular drug, and on what is known about adverse

effects*. The current study will compare the clinical effectiveness, safety and costs of two different most often used regimens in the Netherlands for treatment of acute hypertension in pregnancy, i.e. intravenous labetalol and intravenous nicardipine.

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

- Pregnant women;
- >=18 years of age;
- Severe pregnancy induced hypertension (PIH) or severe pre-eclampsia (PE) at any gestational age. Preeclampsia is defined as hypertension with proteinuria >= 0.3 g/24 hrs.

Exclusion criteria

- Maternal age at eligibility <18 years;
- Fetal abnormalities;
- Multiple pregnancy in current pregnancy;
- Clinically relevant pulmonary edema, defined as pulmonary failure or distress requiring oxygen supplementation (more than 10 liters) and/or pulse oximetry of <94%;
- An allergy to (a substrate of) nicardipine or labetalol;
- A contraindication for the usage of nicardipine or labetalol (asthma, bradycardia, heart blocks, acute chronic heart failure or severe aortic stenosis).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-08-2018
Enrollment:	472
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Labetalol
Generic name:	Labetalol
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Nicardipine
Generic name:	Cardene
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2015-005811-34-NL
CCMO	NL60462.029.17