Platina-trial: labetalol versus nicardipine in acute hypertension in pregnancy.

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON20888

Source

Nationaal Trial Register

Brief title

Platina-trial

Health condition

Pregnancy induced hypertension, preeclampsia, anti-hypertensive treatment, labetalol, nicardipine.

Sponsors and support

Primary sponsor: Amsterdam UMC.

Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Composite adverse neonatal outcome (Respiratory Distress Syndrome, Broncho Pulmonary Dysplasia, Intraventricular Haemorrhage grade 3 or 4, Necrotizing Enterocolitis > stadium 1, Periventricular Leukomalacia, Retinopathy of Prematurity and death before discharge for the neonatal intensive care unit).

Secondary outcome

Secondary neonatal outcomes are preterm birth rate (<34 and <37 weeks), hospital admission and number of days in neonatal intensive care, and hypotension, asphyxia, hypoglycemia and bradycardia if needed treatment.

The main maternal outcome will be defined as a composite of the occurence of eclamptic seizures, cerebral hemorrhage, liver hematoma and rupture, pulmonary edema, admission to the intensive care for ventilation or necessity for intra-arterial monitoring and maternal death. Other outcomes are inadequat control of blood pressure, necessity to use additional or switch to ohter antihypertensive medication, time and dose to blood pressure control.

Study description

Background summary

Compare women with severe hypertension in pregnancy the two most promising drugs: labetalol for its international antihypertensive agent of choice and lack of reflex tachycardia or increased intracranial pressure and nicardipine for its pharmacokinetics with the shortest half-life of antihypertensive drugs and minimal side effects.

Study objective

Nicardipine might decrease adverse maternal and neonatal outcome due to its pharmacokinetics and fewer side-effects.

Study design

Inclusion will take place during pregnancy. Neonatal and maternal data of the admission will be collected.

Intervention

Labetalol iv or nicardipine iv in acute hypertension of pregnancy ≥160/110mmHg.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

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

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 (severe aortic stenosis) or labetalol (asthma, bradycardia, heart blocks, acute chronic heart failure).

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 01-07-2018

Enrollment: 472

Type: Anticipated

Ethics review

Positive opinion

Date: 11-10-2018

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
 NL7339

 NTR-old
 NTR7554

 Other
 60462 : ABR

Study results

Summary results

None.