# 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.