# The NOICH Study.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21014

**Source**
NTR

**Brief title**
NOICH (No IntraCranial Hemorrhage)

**Health condition**

Fetal or Neonatal Alloimmune Thrombocytopenia

### Sponsors and support

**Primary sponsor:** Sanquin Bloodbank Amsterdam provides the trial medication

### Intervention

### Outcome measures

**Primary outcome**

Number of neonates with intracranial hemorrhage.

**Secondary outcome**

Cord blood platelet count at birth.

Other variables studied will be the levels of maternal and neonatal anti-HPA antibodies and IgG, the occurrence of other bleedings in the neonate as well as the necessity and type of

neonatal treatment.

# Study description

### Background summary

The major complication of fetal or neonatal alloimmune thrombocytopenia (FNAIT) is intra cranial hemorrhage (ICH) in the child, resulting in severe morbidity or death.
There are both clinical and experimental indications that intravenous immunoglobulines (IvIG) prevents ICH in the fetus and newborn.

Since the first reported study of treating pregnant women with FNAIT with IvIG, the most commonly used dose has been 1 gram per kilogram bodyweight per week (g/kg/wk). I n one study corticosteroids were added and in another study 2 g/kg/wk has been administered, without apparent benefit (Bussel, 2001; Bussel, 1996).
Given the lack of rationale for the dose of 1 g/kg/wk, the cost of IvIG and the unknown long-term effects of IvIG on the infants, we plan to compare a lower dose with the standard dose IvIG.

The aim of this study is to compare the preventive effect of 0.5 with 1.0 g/kg/week IvIG on FNAIT and ICH, using an international multi-center, randomized controlled trial in patients with FNAIT and a low risk for ICH.

### Study objective

The hypothesis is that 0.5 g/kg/wk of IvIG is as effective as 1.0 g/kg/wk, in the prevention of ICH in FNAIT.

### Intervention

Study group: low dose IvIG (0.5 g/kg/wk);
Control group, standard treatment: high dose IvIG (1.0 g/kg/wk).

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Pregnant women with a subsequent pregnancy after prior pregnancy complicated by HPA alloimmunization who have given birth to a child with a platelet count < 150 x 10 9/l in the first week of life;

2. HPA alloimmunization must have been confirmed by the presence of maternal anti-HPA antibodies and the offending HPA antigen in the fetus or homozygous partner;

3. The biological fathers are either homozygous positive for the HPA-type or heterozygous;

4. In the case of a heterozygous father the platelet antigen genotype of the fetus will be tested before 28 weeks by amniocentesis;

5. At inclusion, the pregnancy is an ultrasonographically proven intrauterine singleton pregnancy with a gestational age between 12 and 28 weeks;

6. All participating patients will give written informed consent after oral and written trial information.

## Exclusion criteria

1. Pregnant women with autoimmune thrombocytopenia;

2. Twins or multiple pregnancies;

3. Fetuses and neonates with major congenital anomalies or chromosomal abnormalities;

4. Women who have previously given birth to children with FNAIT with ICH. Women who have antibodies in the first pregnancy (discovered by chance, or for instance with a sister with FNAIT).

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Single blinded (masking used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2005 |
| Enrollment: | 212 |
| Type: | Actual |

# Ethics review

Positive opinion

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|---|---|
| Date: | 07-09-2005 |
| 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 | NL211 |
| NTR-old | NTR248 |
| Other | : N/A |
| ISRCTN | ISRCTN29462550 |

# Study results

**Summary results**
N/A