The NOICH Study.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21014

Bron
NTR

Verkorte titel
NOICH (No IntraCranial Hemorrhage)

Aandoening

Fetal or Neonatal Alloimmune Thrombocytopenia

Ondersteuning

Primaire sponsor: Sanquin Bloodbank Amsterdam provides the trial medication

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of neonates with intracranial hemorrhage.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	212
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL211
NTR-old	NTR248
Ander register	: N/A
ISRCTN	ISRCTN29462550

Resultaten

Samenvatting resultaten
N/A