

The No IntraCranial Haemorrhage (NOICH) Study

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.noich.org>

Contact information

Type(s)
Scientific

Contact name
Dr D. Oepkes

Contact details
Leiden University Medical Centre
Department of Obstetrics
K6-31, P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 5263360
D.Oepkes@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR248

Study information

Scientific Title

Intravenous immunoglobulin (IVIg) in the treatment of foetal or neonatal alloimmune thrombocytopenia: a prospective, multicentre, randomised trial comparing 0.5 g and 1.0 g IVIg per kilogram bodyweight per week

Acronym

NOICH (No IntraCranial Haemorrhage)

Study objectives

The hypothesis is that 0.5 g/kg/wk of IVIg is as effective as 1.0 g/kg/wk, in the prevention of intracranial haemorrhage (ICH) in foetal or neonatal alloimmune thrombocytopenia (FNAIT).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre randomised single-centre active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Foetal or neonatal alloimmune thrombocytopenia

Interventions

Study group: low dose IVIg (0.5 g/kg/wk)

control group: standard treatment: high dose IVIg (1.0 g/kg/wk)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Intravenous immunoglobulin (IVIg)

Primary outcome measure

Number of neonates with intracranial haemorrhage.

Secondary outcome measures

1. Cord blood platelet count at birth
2. 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

Overall study start date

01/01/2005

Completion date

30/01/2008

Eligibility

Key inclusion criteria

1. Pregnant women with a subsequent pregnancy after prior pregnancy complicated by HPA alloimmunisation who have given birth to a child with a platelet count less than $150 \times 10^9/l$ in the first week of life
2. HPA alloimmunisation must have been confirmed by the presence of maternal anti-HPA antibodies and the offending HPA antigen in the foetus 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 foetus 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

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

212

Key exclusion criteria

1. Pregnant women with autoimmune thrombocytopenia
2. Twins or multiple pregnancies
3. Foetuses and neonates with major congenital anomalies or chromosomal abnormalities
4. Women who have previously given birth to children with FNAIT with ICH
5. Women who have antibodies in the first pregnancy (discovered by chance, or for instance with a sister with FNAIT)

Date of first enrolment

01/01/2005

Date of final enrolment

30/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details

Albinusdreef 2

P.O. Box 9600

Leiden

Netherlands

2300 RC

Sponsor type

University/education

Website

<http://www.lumc.nl/>

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Research organisation

Funder Name

Sanquin Bloodbank Amsterdam (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration