ISRCTN29462550 https://doi.org/10.1186/ISRCTN29462550

The No IntraCranial Haemorrhage (NOICH) Study

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/10/2014	Pregnancy and Childbirth	[ ] 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

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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 x 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
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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