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Intravenous immunoglobulin in the treatment of rhesus disease of the neonate: a randomised double blind placebo controlled trial

Submission date
16/01/2007

Recruitment status
No longer recruiting

Registration date
16/01/2007

Overall study status
Completed

Last Edited
14/01/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL819, NTR832

Study information

Scientific Title

Intravenous immunoglobulin in the treatment of rhesus disease of the neonate: a randomised double blind placebo controlled trial

Acronym
LIVIN

Study objectives
A randomised double blind placebo controlled trial for the use of Intravenous ImmunoGlobulin (IvIG) to reduce the number of exchange transfusions in Rhesus disease of the neonate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Committee of the Leiden University Medical Center on the 12th May 2006 (ref: P06.049).

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rhesus disease

Interventions
Study group: prophylactic IvIG as a single dose of 0.75 g/kg within the first four hours after birth.

Control group: an equal amount of glucose 5% intravenous infusion (placebo).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prophylactic IvIG and glucose 5% intravenous infusion

Primary outcome(s)
1. Use of exchange transfusion (% proportion of children receiving one or more exchange transfusion)
2. Number of exchange transfusion performed per infant

Key secondary outcome(s))

1. Duration of phototherapy (number of days)
2. Maximum serum bilirubin (mmol/l)
3. Change in bilirubin in first 24 hours (%)
4. Change in bilirubin in first 48 hours (%)
5. Use of top-up red cell transfusion in first week of life (% proportion of children receiving one or more red cell transfusion and number of transfusions per infant)
6. Use of simple red cell transfusion after first week and until three months of life (% proportion of children receiving one or more red cell transfusion and number of transfusions per infant)
7. Duration of hospital stay (number of days)

Completion date
31/07/2009

Eligibility

Key inclusion criteria
Neonates of 35 or more weeks of gestation with Rhesus hemolytic disease admitted to the neonatal nursery of the Leiden University Medical Center (LUMC). Rhesus hemolytic disease was defined as:
1. Antibody Dependent Cellular Cytotoxicity-test (ADCC) more than 50%, and
2. Positive direct Coombs test in a Rh (D) or (c) positive fetus/neonate with a Rh (D) or (c) negative mother respectively and a Rh (D) or (c) positive father respectively. Previous intra-uterine transfusions and the presence of additional antibodies besides anti-D and anti-c are not reasons for exclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
Not Specified

Key exclusion criteria
1. Perinatal asphyxia (defined as an Apgar score at five minutes less than three and/or umbilical cord arterial pH less than 7.0)
2. Neonates with hemolytic disease other than Rh (D) or (c)
3. Neonates with Rh hemolytic disease presenting more than 24 hours after birth

Date of first enrolment
01/08/2006

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Center (LUMC) (The Netherlands)

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sanquin Bloodbank Amsterdam (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011	14/01/2021	Yes	No