

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	☐ Prospectively registered
Registration date 16/01/2007	Overall study status Completed	☐ Protocol
Last Edited 14/01/2021	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ 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).

Primary study design

Interventional

Study design

Randomised, placebo controlled, parallel group, double blinded trial

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