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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

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

### Secondary outcome measures
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)

### Overall study start date
01/08/2006

### 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

### Age group
Neonate

### Sex
Not Specified

### Target number of participants

### 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)

### Sponsor details
Department of Pediatrics Division of Neonatology, J6-S
P.O. Box 9600
Leiden
Netherlands
2300 RC

### Sponsor type
Hospital/treatment centre

### Website
http://www.lumc.nl/

### ROR
https://ror.org/05xvt9f17

# Funder(s)

### Funder type
Hospital/treatment centre

### 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

### Study outputs

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