Intravenous immunoglobuline in the treatment of Rhesus disease of the neonate. A randomized double blind placebo controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25873

Source
Nationaal Trial Register

Brief title
LIVIN

Health condition

Rhesus disease, fetal, neonatal

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Department of Neonatology
Source(s) of monetary or material Support: Sanquin Bloodbank Amsterdam

Intervention

Outcome measures

Primary outcome

1. Use of exchange transfusion (%; proportion of children receiving one or more exchange

transfusion);
2. Number of exchange transfusion performed per infant.

Secondary outcome

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 3 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).

Study description

Background summary

Traditional neonatal treatment of Rhesus (Rh) hemolytic disease consists of intensive phototherapy and exchange transfusions (ET). Recently, routine use of intravenous immunoglobulin (IVIg) has been recommended to reduce the number of ET. However, the evidence to recommend prophylactic treatment with IVIg is limited.
The aim of this study is to determine whether the prophylactic use of IVIg reduces the need for ET in neonates with Rh (D) or (c) hemolytic disease. The study design is a prospective randomized double blind placebo controlled trial. All neonates born at our hospital after 35 weeks' gestation and affected with Rh (D) or (c) disease are eligible for the study. After parental informed consent and randomization, neonates will receive conventional treatment + IVIg (0.75 g/kg) or conventional treatment alone. Primary outcome is the proportion of children requiring ET and number of ET performed per infant. Secondary outcomes are duration of phototherapy and hospital stay, serum bilirubin levels (maximum values and change within first 24 and 48 hours), proportion of children requiring top-up red cell transfusion within the first three months of life and the number of red cell transfusions per infant.

Study objective

A randomized double blind placebo controlled trial for the use of intravenous immunoglobulin to reduce the number of exchange transfusions in Rhesus disease of the neonate.

Intervention

Study group: prophylactic IvIG as a single dose of 0.75 g/kg within the first 4 hours after birth;

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

Contacts

Public
Leiden University Medical Center (LUMC), Department of Pediatrics Division of Neonatology, J6-S
P.O. Box 9600

E. Lopriore
Leiden 2300 RC
The Netherlands
+31 (0)71 5262909
Scientific
Leiden University Medical Center (LUMC), Department of Pediatrics Division of Neonatology, J6-S
P.O. Box 9600

E. Lopriore
Leiden 2300 RC
The Netherlands
+31 (0)71 5262909

Eligibility criteria

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) > 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.

Exclusion criteria

1. Perinatal asphyxia (defined as an Apgar score at 5 minutes less than 3 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 > 24 hours after birth.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2006
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	07-12-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL819
NTR-old	NTR832
Other	: N/A
ISRCTN	ISRCTN14013064

Study results

Summary results
N/A