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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25873

Bron
NTR

Verkorte titel
LIVIN

Aandoening

Rhesus disease, fetal, neonatal

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Neonatology
Overige ondersteuning: Sanquin Bloodbank Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2006
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-12-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A