Neurodevelopmental outcome after neonatal hypoglycemia: a multi-center randomized controlled trial comparing intensive treatment versus expectant glucose monitoring in 'high risk' newborns.

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Current clinical practice varies widely, especially for infants with 'moderate' hypoglycemia, due to lack of methodological sound studies. This leads to both over- and under-treatment of hypoglycemic infants. This study-protocol is...

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

Samenvatting

ID

NL-OMON23239

Bron
Nationaal Trial Register

Verkorte titel
HYPO-EXIT

Aandoening

Key words: Hypoglycemia; Blood-glucose; Infant-newborn; Child-development; Developmental-disabilities; Randomized-controlled-trial; Multi-center-studies.
Trefwoorden: Hypoglycemie; bloedglucose; pasgeborene; psychomotere ontwikkeling; gerandomiseerde, gecontroleerde studie; multicenter studie

Ondersteuning

Primaire sponsor: Academical Medical Center, Amsterdam, The Netherlands

Overige ondersteuning: Zon-MW, The Netherlands Organization for Health Research and Development.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is neurodevelopment at 18 months, assessed with the Bayley Scales of Infant Development.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Hypoglycemia is the most common metabolic problem in neonatology: around 25% of all newborns are at risk for neonatal hypoglycemia. In the Netherlands this means that around 40.000 newborns are at risk annually. Because hypoglycemia can lead to permanent brain damage, 'high risk' infants for hypoglycemia are admitted, screened and, if necessary, treated. However, there is still much controversy about the definition of a 'safe' plasma glucose concentration. Currently used limits for hypoglycemia vary between 2.0 and 2.6 mmol/l. As a result, current clinical practice varies widely, especially for infants with 'moderate' hypoglycemia (glucose 2.0-2.5 mmol/l). This leads to both over- and under-treatment of hypoglycemic infants.

Objective: This study-protocol is directed at the comparison of two accepted management strategies at both ends of the current treatment-spectrum of moderate hypoglycemia in 'high risk' newborns: an intensive treatment versus an expectant monitoring strategy.

Study design: Multi-center randomized controlled trial.

Study population: 800 'high risk' newborn infants with moderate hypoglycemia >35 weeks gestational age and birth weight >2000 gram.

Intervention: In the intensive treatment arm the aim is to increase the glucose concentration above 2.5 mmol/l within 3 hours by increasing the carbohydrate intake by oral nutrition and/or intravenous glucose administration. In the expectant arm the aim is to maintain the glucose concentration above 1.9 mmol/l by the usual oral nutrition protocol.

Main study parameters/endpoints: Primary outcome is neurodevelopment at 18 months.

Doel van het onderzoek

Current clinical practice varies widely, especially for infants with 'moderate' hypoglycemia, due to lack of methodological sound studies. This leads to both over- and under-treatment of hypoglycemic infants.
This study-protocol is directed at the comparison of two accepted management strategies at both ends of the current treatment-spectrum of moderate hypoglycemia in 'high risk' newborns: an intensive treatment versus an expectant monitoring strategy.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

In the intensive treatment arm the aim is to increase the glucose concentration above 2.5 mmol/l within 3 hours by increasing the carbohydrate intake by oral nutrition and/or intravenous glucose administration.
In the expectant arm the aim is to maintain the glucose concentration above 2.0 mmol/l by the usual oral nutrition protocol.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants >=35 weeks gestational age and >=2000 gram with one of the four major risk factors for neonatal hypoglycemia:
a. Small-for-gestational-age infants (SGA, birth-weight-for-gestational-age P90);
c. Near-term infants 35 0/7 to 36 6/7 weeks gestational age with a birth weight >2000 gram;
d. Infants of diabetic mothers (IDM).
Birth-weight-for-gestational-age is defined according to the growth charts of the Perinatale Registratie Nederland (PRN).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Infants with serious co-morbidity will be excluded, because their co-morbidity can also affect neurodevelopment:
1. Very preterm infants (<34 6/7 weeks gestational age);
2. Severe perinatal asphyxia: presence of at least 3 of the next criteria:
a. Signs of intrauterine asphyxia, like late decelerations on CTG or meconium stained amniotic fluid
b. Arterial umbilical cord pH <7.10
c. Delayed initiation of spontaneous respirations >5 minutes after birth
d. 5 minute Apgar score <5;
e. Multi-organ failure;
3. Severe perinatal infection: requiring support of vital functions (infants without clinical signs of infection who are treated with antibiotics because of suspected perinatal infection can be included);
4. Respiratory insufficiency requiring respiratory support;
5. Severe hypotension requiring vasopressor support;
6. (Strong suspicion of) a syndrome or major congenital malformations.

Other exclusion criteria:
7. Intravenous glucose administration before randomization;
8. (Strong suspicion of) inborn error of metabolism;
9. (Strong suspicion of) hyperinsulinism, except infants of diabetic mothers;
10. No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	800
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-07-2007
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	NL987
NTR-old	NTR1015
Ander register	. : ZonMW Doelmatigheid 80-007022-98-07406
ISRCTN	ISRCTN79705768

Resultaten

Samenvatting resultaten

Boluyt N, Van Kempen AAMW, Offringa M. Neurodevelopment after neonatal hypoglycemia: a systematic review and design of an optimal future study. Pediatrics. 2006 Jun;117(6):2231-43