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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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30992

Source
ToetsingOnline

Brief title
HYPO EXIT: HYPOglycemia: EXpectant versus Intensive Therapy

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Neonatal and perinatal conditions

Synonym

neonatal hypoglycemia; low blood sugar concentration

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: child development, hypoglycemia, newborn infant, randomized controlled trial

Outcome measures

Primary outcome

Primary outcome is neurodevelopment at 18 months.

Secondary outcome

Secondary outcomes are costs for medical treatment and hospital admission until

18 months of age.

Study description

Background summary

Hypoglycemia is the most common metabolic problem in neonatology: around 25% of all newborns are at risk for neonatal hypoglycemia. 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.

Study 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.
The main research questions are: How does intensive treatment in 'high risk' newborn infants with moderate hypoglycemia compare with expectant glucose monitoring in terms of 1. neurodevelopmental outcome at the age of 18 months; 2. costs for diagnostic tests and treatment of the infant, and hospitalization costs for both the infant and mother; and 3. costs for medical consumption related to neurodevelopmental impairment until the age of 18 months.

Study design

Multi-center randomized controlled trial.

Intervention

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.

Control: In the expectant arm the aim is to maintain the glucose concentration above 2.0 mmol/l by the usual oral nutrition protocol.

Study burden and risks

Burden:
1. Amount and number of blood samples: a minimum of 8 blood samples (7 blood drops and once 0.25 ml) will be taken by heelstick, depending on the course of the glucose concentration in the infant. Only *high risk* newborns will be included, in whom the glucose concentration is routinely checked in current clinical practice.
2. Number of site visits: current clinical practice dictates that these *high risk* infants are admitted to a maternity or neonatal ward for routine glucose monitoring and treatment. Therefore, the hospital admission in the neonatal period is not considered a burden due to the study protocol. Determination of the neurodevelopmental outcome requires one hospital visit (1 hour) at the age of 18 months.
3. For determination of medical costs the parents of the participating infants are asked to fill out a questionnaire at the age of 3-6-9-12-15-18 months.

Benefit and risks: Both treatment strategies have possible (reciprocal) benefit and risks for the participating infants: an intensive treatment strategy can lead to better neurodevelopmental outcome and prevent cases of brain damage (which leads to substantial lifelong morbidity, health care consumption, decreased quality of life, and associated financial cost), whereas an expectant strategy most likely requires less blood sampling, less invasive treatment, shorter hospital stay (of both the infant and the mother) in the neonatal period.

Group relatedness: Neonatal hypoglycemia is a transient problem, occurring in the first postnatal days. In addition, the neonatal period is a unique period from a metabolic and nutritional point of view and for brain development. Therefore, studies on the effects of different treatment strategies on neurodevelopmental outcome will have to be performed in *high risk* newborn infants, thereby involving minors.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants with one of the four major risk factors for neonatal hypoglycemia, who are routinely screened for neonatal hypoglycemia in current clinical practice:
1. Small-for-gestational-age infants (SGA, birth-weight-for-gestational-age 2. Large-for-gestational-age infants (LGA, birth-weight-for-gestational-age >P90);
3. Near-term infants 35 0/7 to 36 6/7 weeks gestational age with a birth weight >2000 gram;

4. Infants of diabetic mothers (IDM).
Birth-weight-for-gestational-age is defined according to the Kloosterman growth charts.

Exclusion criteria

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
3. Severe perinatal infection
4. Respiratory insufficiency
5. Severe hypotension
6. (Strong suspicion of) a syndrome or major congenital malformations;Other exclusion criteria:
7. (Strong suspicion of) inborn error of metabolism
8. (Strong suspicion of) hyperinsulinism, except infants of diabetic mothers
9. No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	800
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL16429.018.07