Insulin sensitivity in appropriate for gestational age and small for gestational age term and preterm infants

Published: 16-07-2007
Last updated: 08-05-2024

To compare insulin sensitivity in full term neonates and preterm neonates at term, and to compare insulin sensitivity in small and appropriate for gestational age infants.

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

Summary

ID

NL-OMON31057

Source
ToetsingOnline

Brief title
Insulin sensitivity in AGA and SGA term and preterm infants.

Condition

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

Synonym
decreased sensitivity to blood sugar regulating hormone, insulin sensitivity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Insulin sensitivity, Preterm, Small for gestational age, Term

Outcome measures

Primary outcome

Primary outcome is insulin sensitivity measured by homeostasis model (IR-HOMA).

This requires a single blood sample for glucose and insulin concentrations.

Secondary outcome

Not applicable.

Study description

Background summary

Diabetes type 2 and other metabolic disorders have become an increasing problem in today*s health care. It has been shown that insulin sensitivity already is reduced at school-age in small for gestational age infants born full-term, and also in premature neonates both appropriate (AGA) and small for gestational age (SGA). This is ascribed to metabolic programming during fetal or early neonatal life. No data are available on insulin sensitivity comparing term and preterm infants, and AGA and SGA infants.

Study objective

To compare insulin sensitivity in full term neonates and preterm neonates at term, and to compare insulin sensitivity in small and appropriate for gestational age infants.

Study design

Observational study.

Study burden and risks

1. 1 ml of blood is needed for measurement of the plasma glucose and insulin concentrations. In order to minimize the burden, the blood sample will be taken simultaneously with a blood sample for clinical reasons (e.g. haemoglobin

concentration before discharge).
2. There is no direct benefit for the study population.
3. Group relatedness: Insulin resistance can progress into diabetes type 2. Knowledge about the underlying pathophysiological mechanisms will lead to the development of preventive and therapeutic strategies. There is a growing body of evidence indicating that growth and nutrition during fetal and early neonatal life plays an important role in the process of metabolic programming. Reduced insulin sensitivity has been shown in children at school age. However, data comparing insulin sensitivity in preterm vs. term infants and AGA vs. SGA infants are lacking. In order to gain insight in the development of insulin resistance, studies will have to be performed in newborn infants, thereby involving minors.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Need for blood sampling on a clinical indication, e.g. for neonatal screening program or before discharge home.
- (Near) term age at the moment of blood sampling (corrected postconceptional age 36-42 weeks)
- Full oral or enteral nutrition (>120 ml/kg/day)

Exclusion criteria

- Uncertain gestational age
- Supplementary intravenous nutrition (parenteral nutrition or glucose infusion)
- Disturbances in glucose metabolism (hypo- or hyperglycemia at a normal carbohydrate intake, or need for insulin therapy to maintain glucose concentration between 2.6 and 8 mmol/l)
- Need for medication interfering with glucose metabolism (vasopressors, corticosteroids)
- Positive family history of type 2 diabetes in first degree relatives
- Perinatal asphyxia (5 minute Apgar score <7)
- Current infection (clinical or laboratory evidence: lethargy or irritability, hypo- or hyperthermia, temperature instability, tachypnea, apnea, bradycardia, hypotension, gastric retention, abdominal distension, pallor, elevated CRP-level, leukocytosis or leukocytopenia and increased number of band neutrophils)
- No informed consent from parents or legal guardians

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	80

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	NL16516.018.07