

Insulin sensitivity in preterm AGA and SGA infants.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28578

Source

NTR

Brief title

N/A

Health condition

Insulin sensitivy, insuline sensitiviteit
Prematurity, prematuriteit
Small for gestational age, dysmaturiteit

Sponsors and support

Primary sponsor: Drs I.A. Zonnenberg

Academisch Medisch Centrum

Neonatologie, H3-213

Meibergdreef 9

1105 AZ Amsterdam

Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Rate of appearance and disappearance of glucose during insulin infusion

Secondary outcome

1. Rate of gluconeogenesis and glycogenolysis;
2. Plasma FFA concentrations;
3. Plasma concentrations of insulin, cortisol and adiponectin.

Study description

Background summary

Low birth weight neonates and premature neonates generally have a decreased insulin sensitivity in childhood. In pathogenesis of decreased insulin sensitivity intra uterine and postnatal factors may play an important role. No data are known if there are yet any differences at birth in insulin sensitivity in premature appropriate for gestational age (AGA) infants and premature small for gestational age (SGA) infants, suggesting influence of intra uterine factors. Research question is: Is insulin sensitivity in premature SGA infants decreased in relation to insulin sensitivity in premature AGA infants at day 2?

Study objective

Insulin sensitivity is already reduced at birth in preterm SGA infants, compared to preterm AGA infants.

Intervention

Not applicable. Observational study

Contacts

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Eligibility criteria

Inclusion criteria

1. Premature infants 28-32 weeks gestational age;
2. Presence of a (central) venous and arterial catheter for clinical reasons;
3. For preterm SGA infants: growth retardation caused by placental insufficiency, assessed by maternal history (pregnancy induced hypertension, preeclampsia), and confirmed by Doppler flow measurements of the umbilical arteries (Pulsatility index, PI, $>+2$ SD for gestational age, measured on two occasions)

Exclusion criteria

1. For preterm SGA infants: growth retardation based on other causes (e.g. congenital infections, congenital malformations);
2. Major congenital malformations;
3. Severe perinatal asphyxia defined as 5 minute Apgar score <7 ;
4. Severe disturbances of glucose metabolism (glucose intake <4 or >8 mg.kg⁻¹.min⁻¹, or need for insulin therapy to maintain the glucose concentration between 2.6 and 8 mmol/l);
5. Severe respiratory distress. Mild ventilatory support is allowed:
 - a. nCPAP with maximum FiO₂ of 0.40, maximum PEEP 6 cm H₂O;
 - b. SIMV with maximum inspiratory peak pressure of 18 cm H₂O and maximum FiO₂ of 0.40;
 - c. HFOV with maximum continuous distending pressure of 12 cm H₂O and maximum FiO₂ of 0.30;
6. Need of vasopressor support for hypotension;
7. Treatment with systemic corticosteroids;
8. Clinical or laboratory evidence of sepsis: 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;
9. Low haemoglobin level at the study days with need for a blood transfusion;
10. Positive family history for type 2 diabetes in first degree relatives;
11. No informed consent from parents or legal guardians.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2007
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion	
Date:	05-02-2007
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

NTR-new

NTR-old

Other

ISRCTN

ID

NL874

NTR888

: N/A

ISRCTN45943101

Study results

Summary results

N/A