

Insulin sensitivity in preterm AGA and SGA infants.

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

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

Samenvatting

ID

NL-OMON28578

Bron

NTR

Verkorte titel

N/A

Aandoening

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

Ondersteuning

Primaire sponsor: Drs I.A. Zonnenberg
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1105 AZ Amsterdam

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Rate of appearance and disappearance of glucose during insulin infusion

Toelichting onderzoek

Achtergrond van het onderzoek

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?

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

Not applicable. Observational study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2007
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	05-02-2007
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	NL874
NTR-old	NTR888
Ander register	: N/A
ISRCTN	ISRCTN45943101

Resultaten

Samenvatting resultaten

N/A