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

Submission date	Recruitment status	[X] Prospectively registered
26/02/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/02/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2021	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof H P Sauerwein

Contact details
Academic Medical Centre (AMC)
Department of Endocrinology and Metabolism, F5-170
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 3061
h.p.sauerwein@amc.uva.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL874 (NTR888)

Study information

Scientific Title
Insulin sensitivity in preterm appropriate-for-gestational-age and small-for-gestational-age infants

Study objectives
Insulin sensitivity is already reduced at birth in preterm Small-for-Gestational-Age (SGA) infants, compared to preterm Appropriate-for-Gestational-Age (AGA) infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Central Committee on Research inv. Human Subjects on the 30th January 2006 (ref: P05.1488C).

Study design
Observational study

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Small for gestational age, prematurity, insulin sensitivity

Interventions
Methods used:
1. Glucose concentration: this will be measured with the glucose oxidase method using a Beckman Glucose Analyzer 2 (Beckman, Fullerton, CA)
2. Insulin: this will be determined with a chemiluminescent immunometric assay (Immulite 2000, Diagnostic Products Corporation, Los Angeles, USA)
3. Free Fatty Acid (FFA) concentration: this will be determined with an enzymatic colorimetric method (NEFA-C test kit, Wako Chemicals GmbH, Neuss, Germany)
4. Cortisol: this will be determined with a chemiluminiscent immunoassay (Immulite 2000,

Diagnostic Products Corporation, Los Angeles, USA)
5. Adiponectin: this will be determined by a radioimmunoassay (Linco, St. Charles, USA)
6. Stable isotope measurements: Newborns are infused with [U-13C] glucose and [2-13C] glycerol. Isotope dilution and label incorporation will be determined by gas chromatography mass spectrometry (GCMS) and mass isotopomer distribution analysis (MIDA) in glucose, isolated from plasma

Calculations:
1. Rate of appearance (Ra) of glucose during steady state is calculated by the isotope dilution technique from the [U-13C] enrichment of glucose, using calculations for steady state kinetics, adapted for the use of stable isotopes: Ra = (Ei/Ep) × I, where Ei and Ep are the enrichments of infusate and plasma respectively, and I is the infusion rate of [U-13C] glucose
2. Rate of disappearance (Rd): rate of exogenous glucose infusion plus the rate of endogenous glucose production
3. Endogenous glucose production: Rate of appearance minus rate of exogenous glucose infusion
4. Absolute gluconeogenesis: fractional gluconeogenesis (measured by MIDA) times rate of appearance
5. Glycogenolysis: Endogenous glucose production minus absolute gluconeogenesis

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of appearance and disappearance of glucose during insulin infusion

Secondary outcome measures
1. Rate of gluconeogenesis and glycogenolysis
2. Plasma Free Fatty Acid (FFA) concentrations
3. Plasma concentrations of insulin, cortisol and adiponectin

Overall study start date
01/04/2007

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Premature infants 28 to 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] more than +2 Standard Deviation [SD] for gestational age, measured on two occasions)

Participant type(s)

Patient

Age group
Neonate

Sex
Not Specified

Target number of participants
16

Key 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 five minute Apgar score less than seven
4. Severe disturbances of glucose metabolism (glucose intake less than 4 or more than 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. nasal Continuous Positive Airway Pressure (nCPAP) with maximum Fraction of Inspired Oxygen (FiO2) of 0.40, maximum Positive End Expiratory Pressure (PEEP) 6 cm Water (H2O)
b. Synchronised Intermittent Mandatory Ventilation (SIMV) with maximum inspiratory peak pressure of 18 cm H2O and maximum FiO2 of 0.40
c. High Frequency Oscillatory Ventilation (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 C- Reactive Protein (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 two diabetes in first degree relatives
11. No informed consent from parents or legal guardians

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Diabetes Fonds Nederland (The Netherlands)

Sponsor details
Stationsplein 139
Amersfoort
Netherlands
3818 LE
-
info@diabetesfonds.nl

Sponsor type
Research organisation

Website
http://www.diabetesfonds.nl/

ROR
https://ror.org/04ch2g225

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration