

Neonatal C-peptide concentration in urine: is it related to birthweight and glucose values on the first day of life or parameters of carbohydrate metabolism in non-diabetic mothers

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to determine the correlation of fetal hyperinsulinemia (measured by urine c-peptide) and maternal indicators of glucose-regulation with neonatal birth weight and postpartum glucose concentration of macrosomic infants of non-diabetic mothers

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

Summary

ID

NL-OMON30164

Source

ToetsingOnline

Brief title

neonatal c-peptide concentration urinary of large-for-date children

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions

Synonym

high birthweight, large-for-gestational-age

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: valt onder reguliere gezondheidszorg

Intervention

Keyword: c-peptide, hypoglycemia, large for gestational age, mothers, non-diabetic

Outcome measures

Primary outcome

birth weight, urine C-peptide, glucose concentration, fructosamine, HbA1c

Secondary outcome

not applicable

Study description

Background summary

LGA infants are at greater risk for developing postnatal hypoglycemia. Fetal growth during pregnancy is influenced by many different factors, such as maternal hyperglycemia. In response to this maternal hyperglycemia, fetal hyperinsulinemia develops. Previous studies have shown that this hyperinsulinemia plays a role in fetal macrosomia, as insulin is an important growth factor. C-peptide is secreted by the pancreas in equimolar quantities to insulin, as both derive from pro-insulin. Therefore, the concentration of C-peptide can be used as an indicator of beta cell secretion of insulin. C-peptide is excreted in urine. Previous studies have shown a positive correlation between C-peptide in cord blood and birth weight, also in children born from non-diabetic mothers. We want to determine if C-peptide concentration in urine is correlated to birthweight and postpartum hypoglycemia of LGA infants of non-diabetic mothers. Furthermore we want to investigate if there is a relation between the neonatal C-peptide and glucose concentration postpartum and the maternal concentration of fructosamine and HbA1c, as both are indicators of glucose regulation.

Study objective

to determine the correlation of fetal hyperinsulinemia (measured by urine c-peptide) and maternal indicators of glucose-regulation with neonatal birth

weight and postpartum glucose concentration of macrosomic infants of non-diabetic mothers

Study design

This is a monocentre prospective study which will take place in Medisch Spectrum Twente. Urine C-peptide and postpartum glucose concentrations will be measured of macrosomic infants of non-diabetic mothers. Measurement of glucose concentration is standard in these infants. Furthermore, maternal concentrations of fructosamine and HbA1c will be determined.

Statistical analysis will be used to show if neonatal urine c-peptide and maternal fructosamine/HbA1c concentrations correlates to birthweight and postpartum glucose concentrations of the infant.

Study burden and risks

The risks of urine sampling and blood withdrawal are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

large-for-gestational-age

Exclusion criteria

diabetic mother

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2007

Enrollment: 40

Type: Actual

Ethics review

Approved WMO

Date: 18-12-2006

Application type: First submission
Review commission: METC Twente (Enschede)

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	NL13770.044.06