Birth weight, fat distribution, body composition and insulin resistance in South Asian and Dutch neonates in The Hague

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

Summary

ID

NL-OMON29841

Source
ToetsingOnline

Brief title
InDIA: Indian and Dutch Infants and their Anthropometry

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: GGD Den Haag

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: insulin resistance, neonatal anthropometry, Netherlands, South Asian babies

Outcome measures

Primary outcome

The primary endpoints will be measures of neonatal anthropometry and insulin resistance in South-Asian and indigenous Dutch neonates. Comparing these will show if the *thin-fat* insulin resistant phenotype can be found among South Asian neonates in The Hague. Other endpoints concern the feasibility and utility of the methods that will be used in the main study.

Secondary outcome

The development of a food frequency questionnaire for pregnant South Asian women

Study description

Background summary

The prevalence of type 2 diabetes is very high among South Asians in The Hague and in other parts of the world. The causes of this high prevalence are unclear. One of the proposed theories is the *fetal origins*-hypothesis, which proposes that persistent metabolic and structural changes caused by fetal undernutrition (due to maternal malnutrition) increase the risk of type 2 diabetes and cardiovascular disease. Nowadays there is much support and some evidence for the idea that the high diabetes and high cardiovascular risk among South Asians is related to fetal developmental issues. For example Indian babies are among the smallest of the world and they are characterized by truncal adiposity and hyperinsulinemia already at birth (*thin-fat Indian baby*). Moreover, in India the results of the Pune Maternal Nutrition Study showed that several micronutrients measured in maternal blood samples and intake of micronutrient-rich foods were related to neonatal anthropometry. The

results of this study can be used to design new preventive measurements.

Study objective

The Municipal Health Service The Hague and the LUMC are planning to conduct a study similar to the one in Pune in The Hague. In the start-up phase of this study we are preparing a pilot study in which we will study anthropometry and insulin resistance in South Asian and indigenous Dutch neonates to asses if the thin-fat insulin resistant phenotype is prevalent in South Asian neonates in The Hague. In this pilot study we will also test the feasibility and the utility of the methods to be used in the main study.

Study design

a longitudinal observational study

Study burden and risks

- At 28 weeks of pregnancy women will be asked to fill in a questionnaire and several measurements will be performed (length, weight, head circumference, mid-upperarm circumference and the four skinfolds). The questionnaire will be more extensive for South Asian women, because they will also have to fill in a food frequency questionnaire. We estimate that filling in the questionnaire will take about 30 minutes for the indigenous Dutch women and 60 minutes for the South Asian women, and performing the physical measurements will take about 15 minutes.
- After delivery cord blood will be taken of women who deliver in the hospital. This isn't painful for neither the mother nor the baby. It's proven to be safe and is used frequently for for example bloodcell-donation.
- Within 72 hours after birth several measurements will be performed on the neonate. Weight and length will be measured, as well as head, abdominal and mid-upperarm circumference and the thickness of the subscapular and triceps-skinfold. These measurements aren't painful and have no risks for the baby. We expect that it will take about 15 minutes to perform these measurements.

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

Surinamese Asian Indian pregnant women of whom both biological parents and the father of the baby are from Surinamese Asian Indian descent.
Indigenous Dutch pregnant women are eligible for inclusion if both biological parents and the father of the baby are indigenous Dutch.
Only neonates with a gestational age of minimal 32 weeks will be included.

Exclusion criteria

- women who expect multiple births (twins, triplets, etc)
- women under the age of 18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-11-2006
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	19-10-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL12684.098.06