Fetal origins of type 2 diabetes in Surinam Hindustani in The Hague

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In the present study we will assess the associations between the nutritional status of Hindustan pregnant women on the one hand and anthropometric and metabolic parameters of their neonates on the other hand.

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

Summary

ID

NL-OMON35642

Source ToetsingOnline

Brief title IndiA: Indian Infants and their Anthropometry

Condition

• Glucose metabolism disorders (incl diabetes mellitus)

Synonym type 2 diabetes

Research involving Human

Sponsors and support

Primary sponsor: GGD Den Haag Source(s) of monetary or material Support: Ministerie van OC&W,Diabetesfonds

Intervention

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

Outcome measures

Primary outcome

The primary endpoints will be measures of the nutritional status of Surinamese

Hindustan women at 28 weeks of pregnancy

and neonatal anthropometry and measures of insulin sensitivity in their

neonates.

Secondary outcome

Not applicable

Study description

Background summary

Diabetes prevalence is extremely high among Hindustani (South Asians) all over the world. In the Netherlands, too, very high figures have been found. The causes of this high prevalence are unknown. Current hypotheses concern among others genetic factors, fetal development resulting in a low birth weight and lifestyle. Many experts think that the high diabetes risk among Hindustani is related to fetal developmental issues. A striking finding in Indian babies is the combination of a low birth weight and a high body fat percentage (the *thinfat Indian baby*). Indian children are characterized by adiposity and hyperinsulinemia already at birth. In India, in the Pune Maternal Nutrition Study (PMNS) associations have been found between the nutritional status of the mother and the fat percentage and distribution of their babies. However, these findings may not be applicable to Hindustan babies in western countries. In Hindustan populations living in western countries, up to now no research has been performed comparable to the PMNS. This is remarkable, as diabetes prevalence among Hindustan immigrants in western countries is even higher than in India. At 28 weeks gestation, we will ask the women (N = 500) to fill in a questionnaire (among others diet, physical exercise, background variables, (family) history of diabetes and other diseases). In addition, blood will be taken (glucose, HbA1c, (HDL) cholesterol, triglycerides, omega-3 and omega-6 fatty acids, vitamin C, D and B12, folate, homocysteine, calcium, magnesium,

zinc, ferritin, C-reactive protein). We will study the associations between these parameters and neonatal parameters (insulin, glucose and triglycerides in cord blood; and birth weight and thickness of skinfolds). These results can be used to design new preventive measurements.

Study objective

In the present study we will assess the associations between the nutritional status of Hindustan pregnant women on the one hand and anthropometric and metabolic parameters of their neonates on the other hand.

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 contains the following parts: a general part, a part on physical exercise and a food frequency questionnaire. We estimate that filling in the questionnaire will take about 60 minutes and performing the physical measurements about 15 minutes. Also blood will be taken from the pregnant women.

- 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

Public GGD Den Haag

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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

Pregnant Hindustani women are eligible for inclusion if both biological parents are of Hindustan Surinam descent, and if the father of their baby and his parents are also of Hindustan Surinam descent.

Exclusion criteria

- women under the age of 18 years
- women who expect multiple births (twins, triplets, etc.)
- babies with a gestational age of 31 weeks or less

Study design

Design

Study type:Observational invasiveMasking:Open (masking not used)Control:Uncontrolled

Primary purpose:

Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	1000
Туре:	Actual

Ethics review

Approved WMO	
Date:	24-12-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	28-12-2009
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	12-11-2010
Application type:	Amendment
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 CCMO ID NL18526.098.07