The Ganesh Study. Risk factors for diabetes and cardiovascular disease in Surinamese South Asian children aged 5 through 12 years and the relation to anthropometry.

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

Summary

ID

NL-OMON35396

Source
ToetsingOnline

Brief title
The Ganesh Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Dienst Onderwijs, Cultuur en Welzijn van de gemeente Den Haag, sector Volksgezondheid en Zorg
Source(s) of monetary or material Support: Externe subsidie bij Fonds NutsOhra aangevraagd

Intervention

Keyword: Cardiovascular risk, Child, Insulin Resistance, South Asian

Outcome measures

Primary outcome

blood pressure

skinfold thicknes at four sites: subscapular, triceps, biceps, suprailiac

Concentration of Total cholesterol, triglycerids, HDL, LDL, glucose en

C-peptide in capillary blood.

Fatpercentage

Secondary outcome

Not applicable

Study description

Background summary

10 percent of all inhabitants in the Hague are of Surinamese South Asian origin. This ethnic group has received special attention from the Municipal Health Service (GGD) since the past 10 to 15 years because of the increased risk of type 2 diabetes mellitus and cardiovascular disease compared to Dutch Caucasians. It is also known that already in childhood South Asians are more insulin resistant and have a higher mean blood pressure than other ethnic groups.
Body composition in South Asians is different from other ethnic groups with regard to muscle mass and fat mass and this difference might play an important role in the increased health risks.

Because of the possible association of health with anthropometry in children the Municipal Health Service in The Hague has initiated the development of growth charts specifically for Surinamese South Asian children as part of the fifth nationwide Growth study that started in 2008 in 53 municipalities in the Netherlands. It is expected that health professionals in Child Health Care and pediatricians with these growth charts will be able to better assess growth in South Asian children.

It is unknown whether cardiovascular risk factors and type 2 diabetes/insulin resistance are already present at a young age in Surinamese South Asian children and it is also unknown whether these risk factors are associated with antropometric data such as Body Mass Index, waist circumference and body fat percentage. Whether there are differences between Dutch and Surinamese South Asian children is also not known.
The Municipal Health Service of the Hague therefore wants to study the relation between risk factors for cardiovascular disease/diabetes and anthropometry. A sample of Surinamese South Asian and Dutch children that have participated in the growth study will be asked to participate.

During the Growth Study Bioelectric Impedance Analysis (BIA) was conducted. With a validated equation for the BIA for both Caucasian and South Asian Children body fatpercentage can be calculated. However, it is not known if these equations can be applied to Dutch and Surinamese South Asian children.

Study objective

Aim of this study is to acquire more insight in the relation between risk factors for cardiovascular disease and type 2 diabetes and anthropometric measures such as BMI, waist circumference and body fat percentage and compare the results between the two participating ethnic groups, Dutch and Surinamese South Asian children.

A secondary objective is to test known BIA equations on the impedance measurments in Caucasian and Surinamese South Asian children with a Dual energy X-Ray Absorptiometry (DXA) scan.

Study design

Observational study

Study burden and risks

The burden and risks associated with participation are minimal. The measurements taken and blood withdrawal is done during one visit. Blood withdrawal is being done with only one finger prick. The finger will also be anaesthetized with a local anesthetic spray.

Parents of young children will be present during the procedures.
The DXA scan will be carried out in a hospital. The radiation dose is minimal, equivalent to 0,038 mSv.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children, aged 5 through 12 years, that have Surinamese South Asian or Dutch ethnicity and have participated in the 5th nationwide growth study

Exclusion criteria

Children:
- that have a growth disorder or that have (had) a disease that affects growth.
- who have diabetes type 1
- that have used oral and inhalation corticosteroids in total during at least a year (when all days that corticosteroids have been used are added)
- that use or have used medication for growth (for example growth hormone)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2009
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2009
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-03-2011
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	ID
CCMO	NL25948.098.08