

Values for lipid profile and markers for insulin sensitivity in 3- to 5-year-old healthy, normal-weight children in the Northern Netherlands.

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To obtain values for lipid profile (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides) and markers for insulin sensitivity (insulin, glucose, HbA1c) in 3- to 5-year-old children.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36895

Source

ToetsingOnline

Brief title

Values for lipids and insulin sensitivity in 3- to 5-year-olds.

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

dyslipidemia, metabolic syndrome

Health condition

metabool syndroom

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: farmaceutische industrie, Ferring

Intervention

Keyword: insulin sensitivity, lipid profile, values

Outcome measures

Primary outcome

Values for: total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides,

insulin, glucose and HbA1c.

Secondary outcome

Not applicable.

Study description

Background summary

The prevalence of childhood obesity is still increasing, also in the Netherlands. Obesity can result in dyslipidemia and insulin resistance which increase the risk on cardiovascular disease and type 2 diabetes at a later age. The combination of cardiovascular risk factors in persons with obesity is known as metabolic syndrome. According to an international consensus, metabolic syndrome cannot be diagnosed in children under the age of ten years. However, cardiovascular risk factors have been identified in children aged 6-9 years. We plan to measure these parameters for clinical reasons in a group of obese children 3- to 5-year-old. To evaluate these results, "normal" values are needed which are not available for this age group.

Study objective

To obtain values for lipid profile (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides) and markers for insulin sensitivity (insulin,

glucose, HbA1c) in 3- to 5-year-old children.

Study design

Observational study. To obtain reliable results for lipid profile and markers of insulin resistance, blood must be drawn after an overnight fast. Therefore, children are needed who undergo a procedure under anesthesia. Since these are children mostly having an adeno/tonsillectomy, we have chosen this group of children.

Children living in the Northern Netherlands, aged 3 to 5 years with normal BMI who are eligible for adeno/tonsillectomy, will be informed by the ENT-specialist about the study while visiting the ENT outpatient clinic. These children are generally in good health with the exception of recurrent ENT infections. Further information about the study will be given by the researcher. Written informed consent will be obtained from the parents or legal caretakers. The adeno/tonsillectomy will take place under complete anesthesia, an intravenous catheter will be inserted by the anesthesiologist during the procedure. Blood will be drawn from the intravenous catheter to determine lipid profile and markers for insulin sensitivity. Thereafter, blood samples will be destroyed.

The study will be performed at the University Medical Center Groningen, from the first of October 2012, to the first of April 2013.

Study burden and risks

Blood will be drawn from the intravenous catheter which is already in place. Total amount of blood drawn will be approximately 2 ml. There are no risks or burden for the patients associated with participation. The study can only be done in this group of patients as this study specifically aims to obtain reference values for lipid profile and markers for insulin sensitivity in this age category.

A possible benefit for the study participants could be the early detection of yet unknown disorders. When values are < -3 SD or > 3 SD, determination of the variable will be repeated in a new blood sample.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

1. Children, aged 3 to 5 years.
2. Normal weight, i.e. body mass index below the international cut-off points for overweight.
Age 3 years: BMI < 17.9 kg/m² (boys) and BMI < 17.6 kg/m² (girls).
Age 4 years: BMI < 17.6 kg/m² (boys) and BMI < 17.3 kg/m² (girls).
Age 5 years: BMI < 17.4 kg/m² (boys) and BMI < 17.2 kg/m² (girls).
3. No chronic disease.
4. Planned for adeno- and/or tonsillectomy.

Exclusion criteria

1. Children under the age of 3 years and children 6 years of age or older.
2. Overweight, i.e. body mass index above the international cut-off points for normal weight.
Age 3 years: BMI * 17.9 kg/m² (boys) and BMI * 17.6 kg/m² (girls).
Age 4 years: BMI * 17.6 kg/m² (boys) and BMI * 17.3 kg/m² (girls).
Age 5 years: BMI * 17.4 kg/m² (boys) and BMI * 17.2 kg/m² (girls).
3. Chronic disease, other than ENT-infections.
4. Familiar hypercholesterolemia diagnosed in one or both parents.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-11-2014

Enrollment: 70

Type: Actual

Ethics review

Approved WMO

Date: 17-01-2013

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL41145.042.12