Advanced Glycation End products in Children with Obesity and Children with Diabetes Mellitus type 1

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Primary objective:To determine sAF levels in children and young adults with T1DM and in children with obesity with or without T2DM and determine the correlation between sAF levels and HbA1c in children and young adults with T1DM and in children with...

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

Summary

ID

NL-OMON40284

Source
ToetsingOnline

Brief title
GLYCOD

Condition

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

Synonym
Advanced Glycation End products. glycated proteins

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Advanced Glycation End products (AGEs), children, diabetes mellitus, obesitas

Outcome measures

Primary outcome

the level of sAF in children and young adults with T1DM and in children with obesity with or without T2DM and the correlation between sAF levels and HbA1c in children and young adults with T1DM and in children with obesity with or without T2DM.

Secondary outcome

correlation between sAF levels and age.

correlation between sAF levels and body mass index (BMI).

correlation between sAF levels and duration of T1DM

correlation between sAF levels and duration of obesity (if traceable).

correlation between sAF levels and duration of T2DM.

correlation between sAF levels and cardiovascular parameters

correlation between sAF levels and lipid profile.

correlation between sAF levels and renal function.

correlation between sAF levels and use of medication for co-morbidities.

correlation between sAF levels and fasting plasma glucose (FPG).

correlation between sAF levels and fasting plasma insulin (FPI).

correlation between sAF levels and insulin resistance (IR).

correlation between sAF levels and impaired glucose tolerance (IGT).

Study description

Background summary

Advanced glycation endproducts (AGEs) are known to accumulate in collagen in human skin. AGEs can be measured invasively in plasma and non-invasively in skin. AGEs in skin can be measured with skin auto-fluorescence (sAF) due to their fluorescent characteristics. Chronic hyperglycemia and oxidative stress result in elevated AGEs levels. Therefore, patients with obesity or diabetes are known to develop elevated levels of AGEs.

Even though glycemic control in patients with diabetes mellitus type 1 (T1DM) is measured by HbA1c levels, AGEs levels also provide information on chronic glycemic control. AGEs, measured as sAF levels are known to be significantly higher in adults with T1DM compared to non-T1DM adults. It has also been shown that sAF levels in adults with T1DM correlate with duration of diabetes and levels of glycated hemoglobin. One study in children demonstrates a correlation between HbA1c and AGEs measured in plasma. However, until today, very little data has been published regarding these correlations with AGEs measured with sAF in children and young adults with T1DM.

In adult patients with central obesity, significantly higher levels of AGEs have been measured compared to non-obese adults. So far, there are some data on AGEs measured in plasma in children and young adults. However, data on AGEs measured non-invasively with sAF in obese children are scarce.

Correlation between AGEs measured with sAF and HbA1c in adults have been published, but very little data on this correlation is known in children and young adults with T1DM. In addition in obese adults elevated levels of AGEs have been demonstrated, whereas data on level of AGEs in obese children are scarce.

Therefore, the rational of the current study is to generate data on levels of AGEs measured with sAF in children and young adults with T1DM and in obese children with or without T2DM.

The primary aim of the GLYCOD study is to determine sAF levels in children and young adults with T1DM and in children with obesity with or without T2DM and determine the correlation between sAF levels and HbA1c. In the current study

sAF levels will be measured with the AGE reader.

Study objective

Primary objective:
To determine sAF levels in children and young adults with T1DM and in children with obesity with or without T2DM and determine the correlation between sAF levels and HbA1c in children and young adults with T1DM and in children with obesity with or without T2DM.

Secondary objectives:
To determine the correlation between sAF levels and age, body mass index, duration of T1DM, duration of obesity, duration of T2DM, cardiovascular parameters, lipid profile, renal function and use of medication for co-morbidities.

Tertiary objectives (exclusively applicable in obesity with or without T2DM-group):
To determine the correlation between sAF levels and fasting plasma glucose (FPG), fasting plasma insulin (FPI), insulin resistance (IR) and impaired glucose tolerance (IGT).

Study design

cross-sectional observational study.

Study burden and risks

Burden
The AGEs will be measured non-invasively with sAF during the regular anthropometric measurements at the out-patient clinic. The measurement will prolong the time of measurements with approximately five minutes. No extra hospital visits are needed, since the measurement will be done during the regular visits at the out-patient clinic. Additional determinants will be collected from medical charts, preferable at the day of the sAF measurement or at the most nearest date to the sAF measurement, with a maximum of 90 days from the sAF measurement.

Risks
Up to date no risks are known from sAF measurement with the AGE reader in children with diabetes. The AGE reader has been used safely in adult studies in patients with T1DM, T2DM or obesity.1,8

Benefit
The participants will gain no benefit from participating in this study.

Group relatedness
Until today very little data exist on sAF levels in children with T1DM and in children with obesity with or without T2DM and the correlation between sAF levels and glycemic control; duration of T1DM and T2DM, and duration of obesity in children. Therefore, it is essential to obtain sAF levels in these specific paediatric populations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

-<24 years of age

AND
-Diabetes Mellitus Type 1 OR Obesity

Exclusion criteria

-A dark-colored skin with a reflectance below 12%, measured with the AGE Reader.
-Use of sun protection cream up to 5 days or self tanner up to 14 days before examination.

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):	23-09-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL45664.100.13