# Advanced glycation end products (AGE) measured by skin autofluorescence and the association with vascular compliance in children with type 1 diabetes.

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The aim of this study is to investigate if changes in vascular compliance in children with type 1 diabetes are related to endothelial markers and to changes in skin AGE and to investigate whether patients at risk to develop cardiovascular disease...

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

## Summary

### ID

NL-OMON40440

**Source** ToetsingOnline

#### **Brief title**

Skin AF en vascular compliance in DM1 children

## Condition

- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym** Type 1 Diabetes Mellitus

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: UMCG

**Source(s) of monetary or material Support:** Geld gedoneerd aan de Beatrix Kinderkliniek door derden voor verrichten van onderzoek bij kinderen met diabetes

### Intervention

Keyword: advanced glycation end products, cardiovascular complications, children, diabetes

### **Outcome measures**

#### **Primary outcome**

AGE-measurement, vascular compliance and endothelial markers in blood.

#### Secondary outcome

Duration of diabetes, HbA1c, BMI, body composition, smoking, lipid

concentrations, microalbuminuria, retinopathy, insulin dosage per kg body

weight, family history of cardiovascular disease, hypertension,

hypercholesterolemie or diabetes.

## **Study description**

#### **Background summary**

Type 1 diabetes is associated with microvascular complications (retinopathy, nephropathy, neuropathy) and macrovascular complications (cardiovascular disease). It is important to identify additional risk factors for cardiovascular disease and to identify atherosclerosis early, to carry out necessary interventions. Skin advanced glycation end products (AGE) measured by autofluoresence have been described as predictor of complications independent of HbA1c in adults with type 1 and type 2 diabetes. In children no association between skin AGE and complications has been made sofar. Early signs of atherosclerosis can be discovered by investigating vascular compliance. Endothelial markers can also be used as early markers for atherosclerosis.

### **Study objective**

The aim of this study is to investigate if changes in vascular compliance in

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children with type 1 diabetes are related to endothelial markers and to changes in skin AGE and to investigate whether patients at risk to develop cardiovascular disease can be identified early in life in order to be able to take preventive measures

#### Study design

In a cross sectional study design, skin AGE will be measured in type 1 diabetic patients in all age groups. Vascular compliance will be measured once in patients of eight years and older, scheduled during regular visits at the paediatric and adolescent diabetes clinic. Blood samples for endothelial markers will drawn combined with their yearly laboratory check-up. Controls for skin AGE and vascular compliance measurements will be age matched friends of the patients.

#### Study burden and risks

Measurements will be performed at a regular outpatient visit and blood samples will be taken only from the patients at their regular yearly laboratory check. AGE measurement takes only a few seconds. For the measurement of vascular compliance using applanation tonometry, subjects must lay still for about 20 minutes. There are no risks for the patients or controls. Benefit for the patients could be that patients with a higher risk for atherosclerosis are identified, so that in the future, interventions decreasing the atherosclerotic risk can be applied.

## Contacts

Public UMCG

Hanzeplein 1 Groningen 9713GZ NL Scientific UMCG

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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**

type 1 diabetes

### **Exclusion criteria**

Other forms of diabetes (type 2, MODY, CFRD etc.) Local skin disease of the lower arm obviating skin autofluorescence measurement Very dark skin influencing skin autofluorescence measurement (reflectance <8%; Fitzpatrick skin type V-VI) Arm too small to cover the window of the AGE reader

## Study design

## Design

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

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Primary purpose:

Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2014
Enrollment:	280
Туре:	Actual

## **Ethics review**

Approved WMO	
Date:	23-09-2014
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 CCMO ID NL47341.042.14