

# A new non-invasive method to assess cardiovascular risks in type 2 diabetic patients and the correlation to treatment types

<b>Submission date</b> 25/08/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/03/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Advanced glycation end products (AGEs) have been identified to play a major role in diabetic complications. They are elevated at high blood sugar concentrations, accumulate slowly throughout the lifespan and contribute to changes in the cardiovascular system (heart and blood vessels). Non-invasive measurement of skin autofluorescence (SAF) estimates the skin tissue AGE content and is able to predict cardiovascular complications, at least in certain patients, which could be used in daily clinical practice. The AGE Reader is a non-invasive monitoring device that uses ultraviolet light. The measurement of AGEs provides an immediate cardiovascular risk prediction within 20 seconds. The AGE Reader has been designed for patient-friendly diagnosis, and because of this allows doctors to practice personalized care and prevent disease (progression). Additionally, the method is convenient, easy to use, and extensively tested. The aim of this study is to assess cardiovascular risks using the non-invasive measurement of skin accumulation of AGEs.

### Who can participate?

Type 2 diabetic patients between 18-70 years old and without skin diseases

### What does the study involve?

The study involves the assessment of AGEs in the skin and correlation to cardiovascular risks. This study also examines the effect of different diabetic treatments on the accumulation of the AGEs in the body.

### What are the possible benefits and risks of participating?

Early diagnosis of cardiovascular risk factors using a non-invasive technique in clinical practice.

### Where is the study run from?

Melk Hospital (Austria)

### When is the study starting and how long is it expected to run for?

February 2019 to February 2021

Who is funding the study?  
Melk Hospital (Austria)

Who is the main contact?  
Dr Nawras Al-Taie  
Nawras.altaie@reflex.at

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Nawras Al-taie

**ORCID ID**  
<https://orcid.org/0000-0003-0522-4583>

**Contact details**  
Melk Diabetes Center  
Melk  
Austria  
3390  
+43 (0)2752/9004-0  
nawras.altaie@reflex.at

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
GS1-EK-2/463-2019

## Study information

**Scientific Title**  
Assessing the accumulation of advanced glycation end products among patients with type 2 diabetes

**Study objectives**  
This is a pilot study to assess the accumulation of AGEs molecules among patients with type 2 diabetes in different treatments groups as part of the cardiovascular risk evaluation.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Approved 26/11/2019, NÖ Ethikkommission (Ethikkommission Für Das Bundesland Niederösterreich  
Am Sitz Des Amtes Der Nö Landesregierung, Gruppe Gesundheit und Soziales - Abteilung Sanitätsdirektion, 3109 St. Pölten, Landhausplatz 1, Austria; +43 (0)2742/9005-9005; post. ethikkommission@noel.gv.at), ref: GS4-EK-2/463-2019

### **Study design**

Observational cohort study

### **Primary study design**

Observational

### **Study type(s)**

Screening

### **Health condition(s) or problem(s) studied**

Type 2 diabetes mellitus

### **Interventions**

AGEs (advanced glycation end-products) are measured using the non-invasive measurement of skin autofluorescence (SAF), which estimates the skin tissue AGEs content and thus may predict cardiovascular complications. The researchers are planning a follow up to 6 months after the first measurement.

### **Intervention Type**

Other

### **Primary outcome(s)**

AGEs accumulation measured using skin autofluorescence at 3, 6 and 12 months

### **Key secondary outcome(s)**

The effect of various treatment types of type 2 diabetes on the accumulation of AGEs measured using skin autofluorescence at 3, 6 and 12 months

### **Completion date**

01/11/2021

## **Eligibility**

### **Key inclusion criteria**

1. Type 2 diabetic patients
2. Aged between 18 and 70 years
3. Moderate to high cardiovascular risk factors
4. Routinely attend the diabetes outpatients service of the Department of Internal Medicine in the Hospital of Melk
5. Patients will be included independently of their medication

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients with dark skin, patients with skin diseases and the use of skin creams, such as agents used to “tan” or “brown” the skin, cannot be included in the study because of limitations to the autofluorescence measurement, which is adjusted to healthy white skin and may give inadequate results in dark skin.

**Date of first enrolment**

01/12/2019

**Date of final enrolment**

01/11/2021

**Locations****Countries of recruitment**

Austria

**Study participating centre****Melk Diabetes Center**

Melk

Austria

3390

**Sponsor information****Organisation**

Melk General Hospital

**Funder(s)****Funder type**

Hospital/treatment centre

## Funder Name

Melk General Hospital

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nawras Al-Taie (Nawras.altaie@reflex.at).

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V4		06/11/2020	No	Yes