

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

Submission date 25/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/03/2021	Condition category Nutritional, Metabolic, Endocrine	<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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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?
Participant information sheet	version V4		06/11/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes