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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

Registration date
25/10/2020

Overall study status
Completed

Last Edited
01/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
01/02/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

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

Sponsor details
Melk Diabetes Center
Krankenhausstraße 11
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nawras.altaie@reflex.at

Sponsor type
Hospital/treatment centre

Website
https://melk.lknoe.at

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Melk General Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/02/2022

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