Development of minimally invasive methodology for diabetyping to personalise treatment to realise remission and reversal of type 2 diabetes.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON53345

Source
ToetsingOnline

Brief title
2DIAREM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
sugar, Type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ancora Health BV,TKI Health Holland,TKI Life Sciences & Health;Ancora Health BV

Intervention

Keyword: Diabetyping, Personalized health, Type 2 Diabetes (remission)

Outcome measures

Primary outcome

The objective of this study is to develop and evaluate algorithms predicting the different diabetypes and the underlying indices (diabetyping) with minimally invasive technology based on capillary sampling using and multi-day CGM with OGTT.

Secondary outcome

The secondary objective is to develop and evaluate minimally invasive diabetyping technology with algorithms based on capillary sampling, venous blood sampling and multi-day CGM upon a standardized snack under real-world conditions.

Study description

Background summary

Lifestyle changes in diet and exercise can reverse type 2 diabetes (T2D), also referred to as T2D remission. Although combined lifestyle interventions for T2D remission are promising, not all persons react similarly to such *one-size-fits-all* interventions. Research has shown that as a result of differences in T2D pathophysiology between individuals, different subgroups of T2D can be identified, that differ in which diet is most beneficial in the recovery of pancreatic beta-cell function. TNO and partners work on the development of the Diabetyping Lifestyle Intervention (DLI) for T2D subtypes

that tailors the combined lifestyle intervention based on organ dysfunction (liver, muscle and/or pancreatic beta cell function) by using the Oral Glucose Tolerance Test (OGTT). Current diabetyping is invasive, needs to take place in a clinical setting, and therefore is not suited for scaling to application in the large T2D population of more than 1 million people. Therefore, less invasive, scalable alternatives are warranted.

Study objective

The main objective of the 2DIAREM study is to develop minimally invasive alternatives of diabetyping. Two alternative sampling methods will be evaluated, capillary sampling and continuous glucose monitoring (CGM). Data collected through these technologies may be used to predict OGTT indices and diabetypes to guide personalized lifestyle interventions for T2D patients. Furthermore, we aim to develop and evaluate the minimally invasive diabetyping technology with algorithms based on capillary sampling and multi-day CGM upon a standardized snack or multi-day CGM only under real-world conditions.

Study design

This research takes a total of 20 days. The study consists of several clinical visits and a home measurement.
Participants are asked to follow their regular lifestyle as much as possible in between. After 3 to 5 days, participants undergo an OGTT in the clinic. On day 8, participants are asked to consume the standardized snack (Snelle Jelle) at home after an overnight fast and perform finger pricks. On day 10, the first sensor expires and the participant applies a new sensor at home (the participant receives an extensive manual and oral explanation for this). On day 17, 18 or 19, the participant will come to the clinic after an overnight fast to consume the standardized snack again with the associated blood tests and the sensor will be removed by an investigator.

Intervention

During the 14 days of monitoring, participants are asked to undergo one OGTT and consume a standardized snack (Snelle Jelle) twice after an overnight fast. In between, the participants are asked to follow their usual lifestyle as much as possible.

Study burden and risks

The burden of this study consist of application and removal of the glucose monitor system, one OGTT and two standardized snacks. The risks associated with participation can be considered negligible, and are mainly associated with the glucose sensor, and the OGTT. The glucose sensor provides a small risk of adverse events including skin irritation, skin infection and skin colouring.

The OGTT poses a small risk of hypo- or hyperglycaemia and can lead to nausea. However, experienced medical professionals are present at the clinic and will closely monitor wellbeing and health status of the study participants. Benefits include that data collected through the technologies (in a less invasive way) may be used to predict OGTT indices and diabetypes to guide personalized lifestyle interventions for T2D patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- - Diagnosed with (pre)diabetes type 2;
o BMI >=27 kg/m2, including a heterogenous group of people with overweight/prediabetes (without glucose lowering medication), and/or type 2 diabetes with or without glucose lowering medication.

- Aged 40 years or older
- Able and willing to sign the informed consent form
- Willing to comply with all study procedures

Exclusion criteria

- Type 1 diabetes
- Latent Autoimmune Diabetes (LADA)
- Skin allergy, eczema or known sensitivity for adhesives
- History of bariatric weight loss surgery
- Planned (bariatric) surgery during the 3 weeks monitoring period with the CGM
- Active cancer or chemotherapy or radiation within 2 years prior to participation
- A condition that would need an MRI during the 3 weeks monitoring period with the CGM
- Planned holiday during the 3 week GCM monitoring period
- (Night)shiftworkers
- Pregnancy and lactation
- Chronic medical condition, treatment, or medication other than diabetes that may affect glucose metabolism (HIV diagnosis, use of steroids or immunosuppressive drugs, etc.)
- 4 or more alcoholic drinks per day on a regular basis or use of recreational drugs

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2024
Enrollment:	57
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2023
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	16-05-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL83666.028.23