Using Continuous Glucose Monitoring and contextual data to increase insight in glucose patterns for individuals with type 2 diabetes

Gepubliceerd: 01-07-2019 Laatst bijgewerkt: 15-05-2024

The study builds on the hypothesis that dense longitudinal personal and functional health data provide optimal information to feed algorithms to give better insight into the influence of contextual data (diet, physical activity, sleep, stress) on…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24321

Bron
Nationaal Trial Register

Verkorte titel
Gluco-Insight

Aandoening

Type 2 diabetes

Ondersteuning

Primaire sponsor: TNO
Overige ondersteuning: TKI LSH, Roche Diabetes Care, TNO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter in this study consists of continuous measured glucose values (mmol/l) measured over a period of 180 days with the use of a CE approved continuous glucose sensor (Dexcom G6).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Type 2 diabetes mellitus (T2D) is not a homogeneous disease; individuals with T2D might benefit from different types of lifestyle interventions, depending on the underlying physiology. Therefore, personalization is of crucial importance for clinical care, as we know that the physiological response to environmental cues (i.e. food, exercise, sleep, stress) and lifestyle interventions (e.g. low-carb or Mediterranean diet) is highly variable between individuals.
Evidence shows that CGM can promote reductions in HbA1c, body weight, and caloric intake, better adherence to a personal eating plan, and an increase in physical activity (PA). When integrated with education, these benefits may be further enhanced. This education becomes particularly powerful when it is personalized, meaning that an individual patient is given information about his or her own glycemic pattern and how this responds to what he or she does (e.g. food intake, PA, and sleep pattern) or experiences (e.g. stress)
Objective: Understand the relation between blood glucose levels and patterns, and contextual data in people with type 2 diabetes
Study design: This study will be an uncontrolled trial with 40 participants. The study will last 27 weeks, and consist of three observational phases (week 2, 13 and 24) and eight intervention phases, with a minimum of 1-week wash-out periods between all phases.
Study population: Insulin-naïve type 2 diabetes patients treated either by metformin or lifestyle advice.
Intervention: During the eight intervention phases participants will be subjected to lifestyle interventions for 4 days, to induce glycaemic variations in response to lifestyle changes including nutrition and exercise. Four different schemes will be used that will each be repeated twice:
1. Hourly physical activity: reducing sedentary time by being physically active for 5 minutes every hour between 09:00 and 17:00
2. After meal walk: 15-minute walk after breakfast, lunch and diner
3. Low carb: diet with a low amount of carbohydrates (sugar and starch).
4. Mediterranean diet: healthy eating plan high in fruits, vegetables, nuts, fish, whole grain and olive oil.
Main study parameters/endpoints: Continuously measured blood glucose values in mmol/l, food intake (food products/meals, macronutrient energy percentage, calories), heart rate (bpm), PA (duration, type), sleep (duration, quality).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden of this study consists of application, use and removal of an implantable glucose monitors, 3 oral glucose tolerance tests and registering contextual factors. During the intervention phases participants are also requested to follow an intervention i.e. regular walking or eating according to the meal plan that is provided.
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.
Benefits include that participants can get more insight in their individual health behaviour and status by self-monitoring food intake, glucose levels, wellbeing and physical activity. Additionally, the use of continuous glucose monitoring and the prescribed interventions are associated with improved health outcome in type 2 diabetes.

Doel van het onderzoek

The study builds on the hypothesis that dense longitudinal personal and functional health data provide optimal information to feed algorithms to give better insight into the influence of contextual data (diet, physical activity, sleep, stress) on glucose metabolism on an individual basis.
The objective of this project is to gain a better understanding of the relation between blood glucose levels and patterns, and contextual data in individuals with T2D. An enhanced understanding of this relation can provide insights on how individuals with T2D can modify their lifestyle to improve glycaemic control.
Additionally, it is aimed to assess how different lifestyle interventions that are proven effective on a population level (Mediterranean diet, low-carb diet, PA) affect glucose fluctuations and specific CGM parameters for individuals.

Onderzoeksopzet

screening (week -1), Visit 0 (week 0), Visit 1 (week 2), Visit 2 (week 13), Visit 3 (week 24), Visit 4 (week 27)

Onderzoeksproduct en/of interventie

Several interventions are introduced to induce a glucose response. These interventions will take a total of 4 days of which 3 are week days and 1 is a weekend day.
The following interventions are performed twice by each participant in a randomized order
1. Hourly physical activity: reducing sedentary time by being physically active for 5 minutes every hour between 09:00 and 17:00
2. After meal walk: 15-minute walk after lunch and diner
3. Low carb: A diet with a low amount of carbohydrates
4. Mediterranean diet: A healthy eating plan with high fruits, vegetable, nuts, fish, whole grain and olive oil.
The exact days at which the intervention is performed is flexible to allow participant to fit it into their daily lives, with the only limit that the different interventions must be at least a

week apart as a wash-out period.

Contactpersonen

Publiek

TNO
Iris de Hoogh

+31611700517

Wetenschappelijk

TNO
Iris de Hoogh

+31611700517

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• BMI 25 – 40 kg/m2, with preference for < 35 kg/m2
• Diagnosed with type 2 diabetes mellitus
• Insulin naïve
• Using either lifestyle and/or metformin for managing their diabetes
• In possession of a Smartphone running on a recent version of iOS or Android
• Able and willing to sign the informed consent form
• Willing to comply with all study procedures

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Insufficient motivation to be in the study
• Unavailability for more than 2 weeks in a row during the study period
• History of bariatric weight loss surgery
• Planned (bariatric) surgery in the upcoming 6 months
• Active cancer or chemotherapy or radiation within 2 years prior to participation

• Chronic medical condition, treatment, or medication other than diabetes that may affect glucose metabolism (HIV diagnosis, use of steroids or immunosuppressive drugs, etc.)
• Chronic anaemia (haemoglobin of 6.2 mmol/l or less)
• Use of antibiotics or fertility treatments within 3 months prior to participation
• Pregnancy or a pregnancy wish
• 4 or more alcoholic drinks per day on a regular basis or use of recreational drugs
• Skin allergy, eczema or known sensitivity for plasters
• Coeliac or Crohns' disease
• Food allergies or intolerances including, gluten, wheat, egg, (pea)nuts, celery, sesame, soy, cacao, glutamate, legumes, coriander, maize, (shell)fish, chicken, beef, pork, lamb, sulphites, lupine, milk and lactose

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-09-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
n/a

Ethische beoordeling

Positief advies

Datum:	01-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49104
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7848
CCMO	NL70771.028.19
OMON	NL-OMON49104

Resultaten

Samenvatting resultaten
-