GLUCOZOND: the impact of dietary intake on continous glucose levels in healthy people

Gepubliceerd: 08-12-2020 Laatst bijgewerkt: 15-05-2024

In is hypothesized that the glycemic response to standardized snacks differs within subjects between different times of the day

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

Samenvatting

ID

NL-OMON26257

Bron
Nationaal Trial Register

Verkorte titel
GLUCOZOND

Aandoening

- endocrine disorders; diabetes complications
- nutritional disorders and metabolic diseases; glucose metabolism disorders (incl. diabetes mellitus)

Ondersteuning

Primaire sponsor: Strategic Program RIVM
Overige ondersteuning: Strategic Program RIVM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The continuous glucose values are determined with Dexcom G6 glucose monitors that the subjects carry with them for 10 days. The primary endpoint of the study is the difference in the incremental area under the glucose response curve: the "incremental area under the curve" (iAUC) at different times of the day around the consumption of standardized snacks. During the entire 10-day period, the test subjects keep a food diary through an app.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:
Reducing glucose level variations through appropriate nutrition could bring significant health benefits to healthy people. However, glucose response to diet (glycemic response) varies between individuals, and is also influenced by factors such as physical activity. It is still unclear to what extent this response also differs within people in relation to the biological (circadian) clock.

Objective of the study:
The study investigates whether the glycemic response to standardized snacks differs within subjects between different times of the day. The study concerns a pilot for a future larger study of more complex aspects of the nutritional and physical activity pattern.

Study design:
A longitudinal crossover design is used in which subjects are followed for a total of 10 days. Each subject is its own control in the sense that differences between the responses at different times within a subject are studied. To prevent confounding by i.e. time, a randomized block design with three arms is used. The arms differ in the pattern of the snack moments: only the order of the times at which standard snacks are taken on the different intervention days is different.

Study population:
The study will be conducted in 24 healthy voluntary test subjects (men and women) between 18 and 65 years old without (self-reported) health problems.

Intervention (if applicable):
Subjects are followed for a total of 10 days. Six of those 10 days are the "intervention days" on which the subjects must adhere to rules. Subjects follow a schedule with set times at which they eat meals and snacks on the 6 intervention days. They then eat a pre-packaged ginger bread bar (the standard snack) at a set time in the morning, afternoon, or evening. In the two hours before and after the specified snack time, the subjects are asked not to eat anything else and only drink water, coffee and / or tea. Furthermore, test subjects are not allowed to exercise or perform heavy (domestic) tasks during these intervention days. The subjects follow their own diet on the other days of the study.

Primary study parameters/outcome of the study:

The continuous glucose values are determined with Dexcom G6 glucose monitors that the subjects carry with them for 10 days. The primary endpoint of the study is the difference in the incremental area under the glucose response curve: the "incremental area under the curve" (iAUC) at different times of the day around the consumption of standardized snacks. During the entire 10-day period, the test subjects keep a food diary through an app.

Secundary study parameters/outcome of the study (if applicable):
To explore the relationship with physical activity and nutrition, the test subjects also wear an ActiGraph wGT3X BT accelerometer.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
Subjects visit the RIVM three times: for an intake interview and to sign informed consent; to start the investigation and finally upon completion of the investigation. In addition, they visit a Saltro location to conduct an oral glucose tolerance test; a tube of blood is taken twice. Subjects are asked to undergo an oral glucose tolerance test. This test can be experienced as unpleasant by some people. In addition, the limited risks associated with a blood test apply. Rules regarding nutrition and exercise are imposed during 6 days. The risks of this study are expected to be minimal. The glucose monitor and the accelerometer are regularly used for scientific research. The glucose monitor is also used in the care of patients with diabetes. In the glucose monitor, mild local reactions to the sensor, such as redness, itching and bruising, were reported in some of the subjects. Participation in the study takes the test subject around 20 hours in total. There are no direct personal benefits for the test subjects. Test subjects receive a travel allowance and an allowance in the form of a gift voucher of 75 euros when completing the study. Test subjects can, if they wish, receive a feedback from the personal data collected during this study. Conducting this pilot study can provide a better knowledge base on glucose patterns in healthy people and how these are influenced by diet.

Doel van het onderzoek

In is hypothesized that the glycemic response to standardized snacks differs within subjects between different times of the day

Onderzoeksopzet

10-day measurement period starts in February or March 2021

Onderzoeksproduct en/of interventie

Subjects are followed for a total of 10 days. Six of those 10 days are the "intervention days" on which the subjects must adhere to rules. Subjects follow a schedule with set times at which they eat meals and snacks on the 6 intervention days. They then eat a pre-packaged ginger bread bar (the standard snack) at a set time in the morning, afternoon, or evening. In the two hours before and after the specified snack time, the subjects are asked not to eat anything else and only drink water, coffee and / or tea. Furthermore, test subjects are not allowed to exercise or perform heavy (domestic) tasks during these intervention days. The subjects follow their own diet on the other days of the study.

Contactpersonen

Publiek

RIVM
Tessa van der Maaden

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- BMI 18.5-30 kg/m2
- 18-65 years old
- Subjectively health

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Illiteracy
- Not being able to give informed consent
- Do not have a doctor
- Use of medicines that can influence glucose levels: such as beta-adrenergic receptor antagonists ('betablockers')
- Pregnancy, breastfeeding, women who are actively trying to conceive
- Acute and / or chronic disease that prevents the test subject from adhering to the research protocol.
- Metabolic and / or hormonal disorders, such as diabetes mellitus
- Swallowing problems, delayed stomach emptying
- Allergies for the standard snack, such as gluten intolerance
- Practicing extreme sports (for example, marathon, triathlon)

- Practicing a very physically demanding job such as in construction.
- Smoking
- Known allergic skin reaction during the use of continuous glucose monitoring or patches in general

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-02-2021
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49546
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9113
CCMO	NL71117.100.20
OMON	NL-OMON49546

Resultaten