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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26257

Source
NTR

Brief title
GLUCOZOND

Health condition

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

Sponsors and support

Primary sponsor: Strategic Program RIVM
Source(s) of monetary or material Support: Strategic Program RIVM

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To explore the relationship with physical activity and nutrition, the test subjects also wear an ActiGraph wGT3X BT accelerometer.

Study description

Background summary

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.

Study objective

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

Study design

10-day measurement period starts in February or March 2021

Intervention

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.

Contacts

Public
RIVM
Tessa van der Maaden

0302743256
Scientific
RIVM
Tessa van der Maaden

0302743256

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	08-12-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49546
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results