THE INFLUENCE OF FOOD ORDER ON POSTPRANDIAL BLOOD GLUCOSE LEVELS IN CHILDREN WITH TYPE 1 DIABETES.

Published: 18-05-2016
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Primary Objective: To investigate the effect of food order on postprandial blood glucose levels in children with type 1 diabetes, using 2 isocaloric meals. A standard meal with all macronutrients (carbohydrates, proteins and fat) combined will be...

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON42890

Source
ToetsingOnline

Brief title
Food Order and Postprandial Glucose Level.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, type 1 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Haga Ziekenhuis locatie Juliana Kinderziekenhuis
Source(s) of monetary or material Support: Subsidie is aangevraagd bij het Wetenschapsfonds van het HagaZiekenhuis.

Intervention

Keyword: Children, Food order, Glucose level, Type 1 diabetes

Outcome measures

Primary outcome

Difference in peak glucose level in the 3-hour clinical observation period following the standard and test meal.

Secondary outcome

Glucose excursion at each 30-minute intervals from baseline till 180 minutes after each meal, number of hypoglycaemic events (blood glucose level < 3.8 mmol/l) in the 3-hour clinical observation period following the meals, time to peak glucose level and the proportion of time blood glucose level exceeded 10 mmol/l.

Study description

Background summary

Postprandial hyperglycaemia is associated with long-term diabetic complications and mortality. Improving postprandial blood glucose levels might result in a reduction in long-term diabetic complications. The order of consumption of carbohydrates, proteins and fat * and therefore food order * has a significant impact on postprandial blood glucose levels in adults with type 2 diabetes due to delayed gastric emptying, changes in hormonal gastrointestinal response and regulatory peptides. Based on the available data and possible pathophysiological mechanisms in adults with type 2 diabetes, patients with type 1 diabetes might also respond with lower postprandial blood glucose levels when food order is changed. Our hypothesis is that postprandial blood glucose levels will be lower when carbohydrates are consumed after fat and proteins, compared to a meal where all macronutrients are combined (a standard meal).

Study objective

Primary Objective: To investigate the effect of food order on postprandial

blood glucose levels in children with type 1 diabetes, using 2 isocaloric meals. A standard meal with all macronutrients (carbohydrates, proteins and fat) combined will be compared to a meal where proteins and fat are consumed 15 minutes prior to carbohydrates (test meal).
Secondary Objective(s): To assess the additional value of CGMS versus 30-minute capillary blood glucose levels to determine the course of blood glucose levels.

Study design

Randomized, open-labelled, within-subject repeated measures crossover study.

Intervention

Patients will be served 2 meals, separated by 2-3 days. During the standard meal all macronutrients will be consumed together. During the test meal, proteins and fat are separated from the carbohydrate part of the meal. Patients will consume the protein and fat part of the meal first, followed by the carbohydrate part of the meal 15 minutes afterwards.

Study burden and risks

A CGM sensor will be inserted in the abdominal subcutaneous tissue and a physical examination will be performed 1 day prior to study entry. CGMS is considered standard of care for patients on pump treatment and the burden can be regarded as minimal. CGMS requires 2 times per day capillary blood glucose measurements to allow for calibration. These measurement are part of the daily blood glucose checks performed by patients with type 1 diabetes. During the study week, patients and their parent(s) will visit the daycare facility twice for a period of approximately 4 hours. Half of the group will receive a standard meal during the first visit, followed by the test meal 2-3 days later, the other half will receive the test meal first. Capillary blood glucose levels measured by the patient or their parent will be determined every 30 minutes during the 3-hour postprandial period. During this period, patients will be sedentary. The 30 minute interval finger pricks for determination of capillary blood glucose levels is regarded as a negligible burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Children with type 1 diabetes who have been diagnosed for > 1 year.
- Age between 7 and 17 years.
- Glycated haemoglobin (HbA1c) <8.5% (69 mmol/mol).
- BMI < +1.8 Standard Deviation Score (SDS) for age.

Exclusion criteria

- Coexisting medical problems such as celiac disease.
- Thyroid function test last determined > 1 year ago.
- Dietary restrictions.
- Fasting blood glucose level > 10 mmol/l or < 3.8 mmol/l requiring intervention during the morning of study days.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-07-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	18-05-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-06-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21988
Source: NTR
Title:

In other registers

Register	ID
Other	Aangemeld bij Nederlands Trial Register, nummer volgt binnen 4 weken.
CCMO	NL57065.098.16
OMON	NL-OMON21988