The influence of food order on postprandial blood glucose levels in children with type 1 diabetes.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21988

Source
Nationaal Trial Register

Health condition

Type 1 diabetes.

Sponsors and support

Primary sponsor: Haga Hospital
Leyweg 275, 2545 CH The Hague,
The Netherlands

Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Glucose excursion at 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

Rationale: 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. The influence of food order on postprandial blood glucose levels in children with type 1 diabetes is unknown. Our hypothesis is that postprandial blood gluocse levels, measured by capillary blood glucose measurements (finger pricks) and a Continuous Glucose Monitoring System (CGMS), will be lower when carbohydrates are consumed after fat and proteins, compared to a meal where all macronutrients are combined (a standard meal).

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: Open-labelled, within-subject repeated measures crossover study.

Study population: Children with type 1 diabetes between 7 and 17 years of age.

Intervention: Patients will be served a standard meal with all macronutrients combined during the 1st day of study entry. Two to three days after, patients will be served a meal where proteins and fat are separated from the carbohydrate part of the meal. Patients will eat this the protein and fat part of the meal first, followed by the carbohydrate part of the meal 15 minutes afterwards.

Main study parameters/endpoints: Primary outcome measure: peak glucose level. Secondary study parameters: 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

This study aims to evaluate the effect of order of carbohydrates, protein and fat intake on postprandial blood glucose levels in children with type 1 diabetes. Our hypothesis is that postprandial blood glucose levels, measured by capillary blood glucose measurements (finger pricks) and CGMS, will be lower when carbohydrates are consumed after fat and proteins, compared to a meal where all macronutrients are combined (a standard meal).

Study design

Capillaire bloedglucose elke 30 minuten.
CGMS.

Intervention

A CGM sensor (Dexcom G5 Mobile CGM®) will be inserted 1 day prior to study entry. All patients and their parents will receive training in CGMS day-to-day management.
After insertion and education on CGMS is completed, patients will undergo a general physical exam – height, weight, examination of heart, lungs and abdomen, and Tanner staging – and have their HbA1C level determined by finger prick using their own blood glucose meter. At the same time, patients' home blood glucose meter will be validated against laboratory blood glucose level and the blood glucose level will be used for calibration of CGMS.

After an overnight fast, patients will come to the daycare clinic of our hospital around 9 am.

Fifteen minutes prior to both meals, patients will check their capillary blood glucose level with their own glucose meter. The insulin dose for each patient will be determined for the carbohydrate content using each participant’s individualized insulin-to-carbohydrate ratio. The short acting insulin bolus will be administered 10 minutes prior to meal consumption as per home regimen via subcutaneous injection or a standard bolus via the insulin pump.

Both meals will consist of a slice of brown bread with 15 gr of jam, 50 gr of cheese and 50 gr of sliced chicken breast, with 150 ml of orange juice. Patients will consume the standard meal in 20 minutes.

During the test meal, patients will eat the cheese and sliced chicken breast first within 10 minutes (protein and fat part of the meal), followed by the slice of brown bread and orange juice 15 minutes afterwards (carbohydrate part of the meal).

During the 3-hour postprandial period, patients will be sedentary (read, play videogames on a tablet or laptop, or watch television).

Capillary blood glucose levels, measured by the patient or their parent, will be determined every 30 minutes during the 3-hour postprandial period.

At the completion of the study, CGMS sensor will be removed.

Contacts

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Eligibility criteria

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
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	40
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 42890
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5011
NTR-old	NTR5784
CCMO	NL57065.098.16
OMON	NL-OMON42890

Study results

Summary results
Not applicable for this study.