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Effect of sucrose-sweetened mixed berry puree on postprandial glucose and insulin response

Submission date	Recruitment status	[ ] Prospectively registered
16/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2010	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Leo Niskanen

Contact details
Neulaniementie 2 L 6
Kuopio
Finland
70210
leo.niskanen@kuh.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
POFE2 4232

Study information

Scientific Title

Effect of sucrose-sweetened mixed berry puree on postprandial glucose and insulin response: A randomised, single-blind, placebo-controlled, cross-over single-centre study

Study objectives
The primary aim was to investigate the effect of mixed berry puree made from bilberries, blackcurrants, cranberries and strawberries on postprandial plasma glucose concentrations after a 35 g sucrose load in healthy subjects. The secondary aim was to investigate the effect of berry puree on postprandial insulin response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Hospital District of Northern Savo approved the study protocol 27 October 2009 (DNRO 106/2009)

Study design
Randomised single blind placebo controlled crossover single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Postprandial glycaemia

Interventions
Test meal: 150 g of berry puree made from equal amounts of bilberries, blackcurrants, cranberries and strawberries with 35 g sucrose and 120 ml of tap water.
Control meal: 250 ml of oral sucrose load with similar amounts of available carbohydrates (glucose, fructose and sucrose) than test meal.

Subjects participated in two 2-h meal tolerance tests in a random order, on separate days, with a washout period of at least 5 days. Subjects were tested at the same time of day under similar conditions and acting as their own controls. The experiment began in the morning after a 10-12 h overnight fast. Subjects were advised to consume the test meal steadily within 15 min.
The study subjects were instructed to maintain their diet, body weight and living habits throughout the study, to refrain from intensive physical activity on the day before the test days and abstain from alcohol two days before the test days, and to avoid berries and chocolate in

the prior evening meal. In addition, in the evening before the test day each subject was told to consume a meal of choice and repeat that meal before the second test. Smoking was prohibited on the morning before the test and during the test meal.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Plasma glucose concentrations analysed from fingertip capillary and venous blood samples taken within 20 min before the ingestion of meal and at 15, 30, 45, 60, 90 and 120 min after starting the ingestion of meal.

Secondary outcome measures
1. Serum insulin concentrations analysed from venous blood samples taken within 20 min before the ingestion of meal and at 15, 30, 45, 60, 90 and 120 min after starting the ingestion of meal
2. Optionally, the following concentrations may be measured at the same time points:
2.1. Plasma cholecystokinin (CCK)
2.2. Glucose-dependent insulinotropic polypeptide (GIP)
2.3. Glugacon-like peptide 1 (GLP-1)
2.4. Peptide YY (PYY)
3. Body weight measured with calibrated digital scale at every study visit after 10-12 h overnight fasting

Overall study start date
28/10/2009

Completion date
03/12/2009

Eligibility

Key inclusion criteria
1. Provision of signed and dated consent prior to any study procedures
2. Men or women aged 18 to 70 years
3. Subject's laboratory evaluation at the screening visit must be within normal limits (with the exception of abnormalities considered as clinically insignificant in the opinion of the study physician)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Subject with type 1 diabetes
2. Subject with type 2 diabetes
3. Subject requiring antiglycemic medication
4. Subject with allergy or sensitivity to an ingredient of the test product
5. Subject with active hepatic, kidney or thyroid disease or disorder except the subjects on thyroid replacement therapy
6. Female subject who is pregnant or lactating
7. Subject with: haemoglobin < 100 g / l, fasting plasma glucose concentration > 7.0 mmol/l, plasma gamma-glutamyl transferase > 2 x upper limit of normal or plasma creatinine > 2 x upper limit of normal at the screening visit.
8. Subject with body mass index > 30
9. Subject who have had myocardial infarction within 6 months prior to screening
10. Subject with unstable angina pectoris
11. Subject who have history of temporal ischemic attack or stroke within six months prior to screening
12. Subject with malignancy within 5 years prior screening (except treated cutaneous basal cell or squamous cell cancer)

Date of first enrolment
28/10/2009

Date of final enrolment
03/12/2009

Locations

Countries of recruitment
Finland

Study participating centre
Neulaniementie 2 L 6
Kuopio
Finland
70210

Sponsor information

Organisation

Finnsugar Ltd (Finland)

Sponsor details
Sokeritehtaantie 20
Kantvik
Finland
02460
kyllikki.kilpi@nordicsugar.com

Sponsor type
Industry

ROR
https://ror.org/02cnwya81

Funder(s)

Funder type
Industry

Funder Name
Finnsugar Ltd (Finland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration