Effects of the food matrix on serum fructose peaks

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To quantify fructose that escapes the portal circulation and appears in the systemic circulation, by measuring serum fructose using ultraperformance liquid chromatography-tandem mass spectrometry (UPLC-MS/MS) within 150 minutes following intake of...

Ethical review	Approved WMO
Status	Completed
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON53397

Source
ToetsingOnline

Brief title
Effect of matrices on serum fructose

Condition

- Hepatic and hepatobiliary disorders
- Vascular hypertensive disorders

Synonym
High blood pressure, Hypertension, Non-alcoholic fatty liver disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fructose, Liver, Matrix

Outcome measures

Primary outcome

The primary study parameter is the fructose peak, defined as the maximal incremental change from baseline.

Secondary outcome

Secondary study parameters include:

1. Systolic and diastolic blood pressure peak, defined as the maximal incremental change from baseline.

2. Serum uric acid peak, defined as the maximal incremental change from baseline.

Study description

Background summary

Epidemiological evidence is accumulating that a high consumption of added sugars is associated with metabolic diseases such as type 2 diabetes. Fructose, one of the principal added sugars, is believed to be the most disadvantageous sugar. Data from a large population-based cohort demonstrated that fructose intake from fruit juice and sugar-sweetened beverages, but not whole fruits, is associated with higher intrahepatic lipid content. A study in mice demonstrated that fast fructose exposure resulted in higher intrahepatic lipid content than slow fructose exposure. The food matrix, i.e. the complex spatial organisation of and interactions between nutrients, may account for the fast versus slow fructose exposure and following health consequences. Therefore we aim to investigate the role of the fructose matrices on serum fructose peaks. We hypothesize that liquid fructose matrices will cause higher serum fructose peaks in comparison to solid fructose matrices.

Study objective

To quantify fructose that escapes the portal circulation and appears in the systemic circulation, by measuring serum fructose using ultraperformance liquid chromatography-tandem mass spectrometry (UPLC-MS/MS) within 150 minutes following intake of fructose-containing matrices.

Study design

This study is an open-label, randomized intervention study.

Intervention

Per visit, participants are provided a food product containing 20 g fructose. This amount of fructose resembles a physiological intake of fructose.

The four fructose-containing food products include:
- Apple;
Jonagold apple, peeled and cored. A validated enzymatic assay (Enzytec* Generic D-Glucose/D-Fructose/Sucrose #E1247, R-Biopharm® AG, Darmstadt Germany) is used to measure fructose content of every individual apple used in the study. On average, 230 g of Jonagold apple contains 20 g fructose.

- Shredded apple;
Jonagold apple, peeled and cored. A validated enzymatic assay (Enzytec* Generic D-Glucose/D-Fructose/Sucrose #E1247, R-Biopharm® AG, Darmstadt Germany) is used to measure fructose content of every individual apple used in the study. On average, 230 g of Jonagold apple contains 20 g fructose. The apple will be shredded using a blender. By shredding the apple, the food matrix, i.e. the physical structure and spatial organisation of molecules, is disturbed.

- Apple juice;
Long shelf life, store bought apple juice (Goudappeltje 100% Puur sap, Appelsientje®) contains juice from the concentrate of seven apples per litre and is shortly heated to allow long storage. Fructose content per pack of apple juice is measured with the enzymatic assay. Approximately 320 ml of apple juice contains 20 g fructose.

- Fructose dissolved in water.
Fructose ($C_6H_{12}O_6$; 1,3,4,5,6-pentahydroxyhexan-2-one); molecular weight 180.15588 g/moll) is a monosaccharide and produced as white crystals or powder, with a sweet taste and no objectionable odours. In solution, fructose is colourless, odourless, and clear to slightly turbid. It is widely used in the food industry. Fructose is produced by NUTRICIA advanced medical nutrition for oral administration

Study burden and risks

Considering the nature of the study, i.e. short-term and low protocol complexity, low health risk, natural product use, small study population (N=18) and healthy study population, the study is regarded as *low/negligible risk*.

Blood withdrawal could cause collapse, bleeding, hematoma, infection or nerve damage. For this reason, blood withdrawal will be performed by experienced staff.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age >= 18 years.
Body mass index (BMI) >=18.5 kg/m2 and <25 kg/m2

Exclusion criteria

- Pregnancy.
- Drugs and/or alcohol abuse.
- Diagnosis of diabetes mellitus.
- (History of) gastrointestinal and/or liver disease.
- (History of [< 5 years]) Ccancer (excluding basal cell carcinoma).
- Physical stress one month prior to inclusion (i.e. post-surgery, trauma that requires medical treatment, or bacterial/viral/fungal infection or extreme psychological stress).
Symptoms of infection include: fever, (excessive) sweating & chills, cough, sore throat, shortness of breath, nasal congestion, diarrhea, vomiting, painful miction, redness/swelling, stomach ache, head ache, and stiff neck.
- Unstable weight for 3 months prior to inclusion (i.e. 5% change in bodyweight)(18).
- Allergy to one of the used food products in the study.
- Inability to provide written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-12-2022
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-02-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL81668.068.22

Study results

Date completed: 23-04-2024

Summary results
Trial ended prematurely