The effects of FRUctose restrIcTion on LivEr SteatosiS; the FRUITLESS study

Published: 23-01-2017
Last updated: 15-04-2024

To quantify the change in hepatic fat (primary objective) and endothelial function, arterial stiffness, plasma lipids, plasma biomarkers of inflammation and endothelial function, and plasma advanced glycation end products (secondary objectives)...

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

Summary

ID

NL-OMON47128

Source
ToetsingOnline

Brief title
The FRUITLESS study

Condition

- Hepatic and hepatobiliary disorders
- Metabolism disorders NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Non-alcoholic fatty liver disease (fatty liver)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nutricia beurs

Intervention

Keyword: Cardiovascular disease, Fructose, Non-alcoholic fatty liver disease

Outcome measures

Primary outcome

Differences in intrahepatic triglyceride content between the intervention and control group.

Secondary outcome

Markers of cardiovascular risk * i.e. endothelial function, arterial stiffness, plasma lipids, plasma biomarkers of inflammation and endothelial function, and plasma advanced glycation end products * between the intervention and control group.

Study description

Background summary

Cardiovascular disease is a major threat to morbidity and mortality in Western society. Evidence has accumulated that nonalcoholic fatty liver disease is an independent risk factor for the development of cardiovascular disease. Fructose plays an important role in the accumulation of fat in the liver as it serves as a substrate for de novo lipogenesis and stimulates hepatic glucose disposal via the disruption of the glucokinase-glucokinase regulatory protein complex. Previous studies have already studied the lipogenic effect of fructose added to standard diet. However, little attention has been paid to the effect of a diet devoid of fructose. Therefore, this study aims to investigate the effects of fructose restriction on hepatic fat accumulation and vascular risk. It is hypothesized that fructose restriction will decrease hepatic fat content and improve vascular status.

Study objective

To quantify the change in hepatic fat (primary objective) and endothelial function, arterial stiffness, plasma lipids, plasma biomarkers of inflammation and endothelial function, and plasma advanced glycation end products (secondary

objectives) after six-weeks of fructose restriction.

For this, two groups will follow a six-week low fructose diet where the amount of fructose restriction will be supplemented by either glucose powder (intervention group) or fructose powder (control group) (with a minimum of 45 gram/day). Vitamin C will be supplemented in both groups to avoid deficiency. At baseline and study closeout several cardiometabolic measurements will be carried out, including magnetic resonance spectroscopy, laser doppler flowmetry, reactive hyperemia peripheral arterial tonometry, carotid femoral pulse wave velocity, blood withdrawal, and an oral glucose tolerance test.

Study design

A double-blind randomized placebo-controlled intervention study.

Intervention

Low fructose diet, where the amount of fructose restriction will be supplemented by either glucose powder (intervention group) or fructose powder (control group) (with a minimum of 45 gram/day).

Study burden and risks

The proposed study diet will be similar to the diet of patients with hereditary fructose intolerance, which will be closely monitored by an experienced metabolic physician. This diet has been proven to be safe. Both glucose and fructose powder are natural products that are well represented in the Western diet. The only invasive test will be blood withdrawal (two times approximately 150 ml), which is associated with minimal health risk. Potential benefits are an extensive screening for nonalcoholic fatty liver disease, cardiovascular risk and type 2 diabetes mellitus, which are treatable entities.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50

Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age *18 years;
- BMI * 28;
- Fatty liver index * 60.

Exclusion criteria

- Medical history of liver disease, such as viral and auto-immune hepatitis.
- (History of) excessive alcohol consumption (defined as > 2 units/day for women, and > 3 units/day for men);
- Use of glucose lowering drugs (including insulin);
- Recent illness;
- Pregnancy and/or lactation;
- Major change in weight and/or physical activity prior to the study;
- Contraindications for MRI (i.e. claustrophobia, heart pacemaker or other electronic devices implanted in the body, history of collapse or seizure);
- Inability to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2017
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-07-2018
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	NL58360.068.16
Other	www.clinicaltrials.gov