The effect of oral Fructose on Intestinal Absorption and micobiome in patients with intestinal failure

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To study the effect of oral/enteral fructose on enterocyte function and on the the gut microbiome and intestinal absorption capacity in patients with short bowel syndrome who are dependent on parenteral nutrition (PN) and/or intravenous (iv) fluids...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malabsorption conditions
Study type	Interventional

Summary

ID

NL-OMON57131

Source
ToetsingOnline

Brief title
FIA

Condition

- Malabsorption conditions

Synonym
intestinal failure

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fructose, Intestinal absorption, Intestinal Failure, microbiome

Outcome measures

Primary outcome

primary outcome is the citrulline generation test (CGT) which reflects

Intestinal Enterocyte Function.

Secondary outcome

Secondary outcomes are microbiome composition and need for PN and iv fluids and

intestinal absorption capacity of nutrients and fluid.

Study description

Background summary

In mice, daily oral fructose intake improved intestinal enterocyte function (IEF) by increased survival of intestinal enterocytes, increased intestinal surface area and intestinal absorptive capacity (IAC). These effects might be beneficial in patients with reduced intestinal absorption such as in patients with short bowel syndrome and Intestinal Failure (IF).

Study objective

To study the effect of oral/enteral fructose on enterocyte function and on the the gut microbiome and intestinal absorption capacity in patients with short bowel syndrome who are dependent on parenteral nutrition (PN) and/or intravenous (iv) fluids.

Study design

single blind, cross-over intervention study.

Intervention

daily oral/enteral fructose versus glucose for 4 weeks. Treatment periods will be separated by a 4 week washout period. The dose of fructose will be

determined in a feasibility study in which we investigate gastro-intestinal tolerance of different doses of oral fructose.

Study burden and risks

patients might experience gastrointestinal complaints to either glucose and/or fructose. These might include increased stoma output/diarrhea or abdominal cramps. Since fructose and glucose are nutrients that are consumed in regular diets, no other side effects are expected. The citrulline generation test has been well tolerated in an earlier study in a similar population and therefore we do not expect side effects. Blood samples will be drawn from a peripheral iv line which might induce mild discomfort. Four visits will be planned to perform all study procedures.
If fructose increases absorptive capacity in patients dependent on PN, this will impact the included particpants directly since treatment with fructose will then be continued after study end. Eligible patients that did not participate in the study will also be offered fructose treatment in case of positive results.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Treated by the TPN and IF Clinic at Amsterdam UMC
• Ability to provide written informed consent (in Dutch)
• Age of 18 years or older
• Dependent on PN or iv fluids
• Stable weight or stable amount of PN/iv fluids during the 3 months prior to start of the study
• Adapted intestinal function,i.e. >=2 years after last small bowel resection (if applicable)
• Duodenum and proximal jejunum in situ
• Short bowel syndrome (< 200 cm small bowel)

Exclusion criteria

• Unable to read and understand the patient information letter and/or study procedures
• Unable to tolerate oral or enteral nutrition
• Ultrashort bowel (<20 cm small bowel)
• Diabetes Mellitus
• Active inflammatory bowel disease
• Systemic scleroderma involving the gut
• Radiation-enteritis
• Endocrine and exocrine pancreatic insufficiency
• Severe renal impairment (creatinine clearance < 25 ml/minute)
• Severe hepatic impairment (> 3 times upperlimit)
• Severe metabolic acidosis
• Severe gastrointestinal motility disorder
• Known fructose intolerance
• A high fructose-intake in regular oral and/or enteral diet (> 35 gram/day)
• Contraindication for use of oral alanin and/ or glutamine
• Contraindication for use of oral fructose
• Body weight < 40 kg (because of CGT)
If patiënts participated in the Feasibility study, they are not allowed to participate in the Pilot study

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	13-11-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85772.018.24