Effect of total parenteral feeding on the postprandial bile acid response

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

Summary

ID

NL-OMON44354

Source
ToetsingOnline

Brief title
TRENT

Condition

- Hepatic and hepatobiliary disorders
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
total parenteral nutritrion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Diabetes fonds

Intervention

Keyword: Bile acid signaling, Postprandial inflammation, Total parenteral nutrition

Outcome measures

Primary outcome

To assess the effect of a parenteral MMT compared to an enteral MMT on

* Postprandial bile acid signalling metabolism

* Postprandial inflammatory responses

Secondary outcome

1. To assess the effect of a parenteral MMT compared to an enteral MMT on

* Glucoregulatory and gut hormones

* Lipid profiles

* Resting energy expenditure

* Appetite and satiety

* Blood pressure

* Body core temperature

2. Assess the correlation between the microbiota composition and postprandial

bile acid signalling.

Study description

Background summary

Total parenteral nutrition (TPN), a life-saving therapy, involves providing nutrition while bypassing the gut. However, the clinical anabolic response to TPN is less pronounced compared with enteral feeding. Also, TPN is associated with significant complications including gut atrophy and parenteral nutrition

associated liver disease (PNALD), which includes steatosis, cholestasis, disrupted glucose and lipid metabolism, cirrhosis, and liver failure. The etiopathogenesis of PNALD remains poorly understood; however, emerging evidence in animal studies suggests that inflammation and bile acid toxicity may contribute to TPN related pathology.

Study objective

In this study, we aim to investigate the difference in the anabolic postprandial bile acid response between an enteral and parenteral mixed meal test (MMT) in healthy lean men. This study is important because it may give a better understanding of the role of bile acids in TPN related pathology. Moreover, we may find a potential therapeutic pathway to prevent or treat the complications of TPN

Study design

The current study is an investigator initiated, single center, observational, crossover study.

Intervention

Subjects will undergo an enteral and a parenteral mixed meal test (MMTs) on different days in random order. The mixed meal test will be performed using Olimel Perifeer N4E (Baxter B.V. Utrecht, The Netherlands), an emulsion for parenteral nutrition containing a mix of glucose with calcium, a lipid emulsion and an amino acid solution with other electrolytes. Before, during and after the MMT, resting energy expenditure (REE) will be measured by indirect calorimetry. Before the first MMT, subjects collect a morning stool sample at home and bring it to the AMC. We will ask participants to fill in online or written dietary diary for 3 days prior to the MMT to ensure the stability and similarity of the gut microbiota. Core temperature will be measured with a body core pill and blood pressure with Nexfin. After each MMT, appetite will be evaluated with the Universal Eating Monitor.

Study burden and risks

Burden
The burden of this study includes a screening visit and 2x 7 hours admissions to the hospital after an overnight fast including an enteral and parenteral MMT with Olimel Perifeer N4E. Several blood samples will be drawn via an intravenous cannula. The Olimel will be administered with a second intravenous cannula (parenteral MMT) and a nasoduodenal tube (enteral MMT). The total amount of blood taken will be 212 ml.

Risks

Olimel perifeer N4E (Baxter, Utrecht, The Netherlands) is registered for use as the lipid component of total parenteral nutrition. Olimel Perifeer N4E is specifically administered via a peripheral cannula (in contrast to central venous catheters) because it has lower energetic density compared to other lipid emulsions. The total lipid infusion in this study is therefore typically low compared to standard daily dosing in patients (20% of total dose).

Insertion of an IV cannula carries the risk of hematoma or phlebitis.

The placement of nasoduodenal tube can lead to respiratory tract infection in case of aspiration of gastric content. However, as subjects are fasted during the placement, this is risk is very small.

Benefits
Subjects will not benefit from participation of this study.

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

- Ability to provide informed consent
- 18 years or older at the time of signing the informed consent
- Body mass index (BMI) 18.5- 25 kg/m2
- Caucasian men
- General good health as determined by medical history, physical examination and blood chemistry by a physician.
-HOMA-IR index: * 2.0 (measured as fasting insulin (pmol/L) x fasting glucose (mmol/L) / 135)

Exclusion criteria

-Major illness in the past 3 months
-Use of any medication
-Gastro-intestinal disease that may influence bile acid metabolism
-History of cholecystectomy or other bile duct abnormalities
-Tobacco smoking
-Drugs abuse
-Alcoholism (>3 units a day)
-Allergy or intolerance to ingredients included in the standardized meals
-Blood chemistry:
*Creatinine >120 µM
*>2 times upper limit reference interval of the following: ASAT, ALAT, bilirubin, GGT and AF.
*Lipid spectrum
-Strenuous exercise for at least 3 days prior to each study day, defined as more than 1 hour of exercise per day.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2018
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2017
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	NL63468.018.17