The effect of oral medium chain triglycerides in healthy individuals

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Objective (pilot): to test if our research set-up allows us to accurately measure uptake and metabolism of oral MCT.Objective (actual study): to test if oral MCT is directly oxidized and/or elongated to LCT under the following conditions: fasted/…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON46931

Source
ToetsingOnline

Brief title
Effect of oral MCT

Condition

- Lipid metabolism disorders

Synonym
but a follow-up study will include Very Long Chain Acetyl-CoA Dehydrogenase deficiency (a fatty acid oxidation disorder), In this study only healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,VKS - Stichting Stofwisselkracht

Intervention

Keyword: beta-oxidation, Medium-chain Triglycerides

Outcome measures

Primary outcome

Actual study:

- 13C enrichment of breath CO2.

- 13C enrichment of C12-22 of plasma fatty acids in plasma: triglycerides (TG), phospholipids (PL), Cholesterol esters (CE), VLDL, LDL, HDL and free fatty acids (FA)

Pilot:

* Establish minimum duration of fasting that enables us to detect appropriate levels of LCT and free fatty acids in plasma.
* Establish duration of oral MCT administration to accurately measure enrichment in plasma fatty acids and breath CO2.
* Establish if one week of wash-out period is sufficient to clear MCT-tracer from plasma.

Secondary outcome

* Resting energy expenditure

Pilot

* Response of plasma metabolites (glucose, pyruvate, lactate, ketones, triglycerides, free fatty acids, insulin, cortisol, acylcarnitines, amino

acids) to 36 hours of fasting

Study description

Background summary

For patients with a disorder of the carnitine cycle or long-chain fatty acid oxidation (lcFAO), a long-chain triglyceride (LCT) restricted diet, enriched with medium-chain triglycerides (MCT), is currently one of the few therapeutic options recommended by physicians. The effect of oral intake and utilization by the body has been poorly understood and some studies even suggest that MCT is elongated to LCT in the body. Since lcFAO patients are unable to oxidize LCT, this could mean that the diet has no benefit compared to a regular diet. Our study intends to test the uptake and metabolic route of oral MCT in healthy subjects under different circumstances. We will first perform a small pilot with one healthy subject to determine the optimal conditions for the actual study. The results of the latter will help to determine the usefulness of MCT in the diet of lcFAO patients.

Study objective

Objective (pilot): to test if our research set-up allows us to accurately measure uptake and metabolism of oral MCT.
Objective (actual study): to test if oral MCT is directly oxidized and/ or elongated to LCT under the following conditions: fasted/fed/exercise.

Study design

Dietary intervention study

Intervention

Medium-chain triglyceride emulsion (liquigen®), tracer: glycerol-tri(octanoate-1,2,3,4-13C4)

Study burden and risks

Pilot (1 subject): After an inclusion and screening visit the subject will take an adjusted fasting test, followed by the test day at least one week later. The adjusted fasting test will be stopped if plasma glucose < 3.5 mmol/l, with a maximum duration of 36 hours.
During the test day the subject will get constant oral infusion via nasogastric tube of MCT-tracer for 6 hours, followed by a combination of MCT-tracer and

regular MCT for an additional 6 hours. The subject will be fasted from the evening before the test, actual starting time depends on adjusted fasting test. Blood and breath samples will be collected frequently throughout the test day. In addition, the clearance of tracer from plasma will be tested, for which the subject will have a vena puncture one week after the test day that will be repeated weekly until there is no tracer left in his plasma. This will take approximately 15 minutes each.
Total amount of time spent on the pilot study will be 48 * - 49 hours, dependent on clearance of the tracer from plasma. Total amount of blood drawn during the study will be 338 ml. The only risks are from placement of the nasogastric tube: pharyngeal discomfort, nose bleed and placement of an IV-cannula: phlebitis, hematoma. Gastrointestinal side-effects in the form of diarrhoea may accompany the use of MCT. There is no risk associated with the experimental use of stable isotopes in humans.

Actual study (6 subjects): Instead of 1 test day the subjects will undergo 2 test days with oral infusion via nasogastric tube of MCT-tracer and regular MCT and the other in combination with a combination of oral MCT/ carbohydrates/ protein. Both test days will include 30 minutes of exercise on a bicycle ergometer. The results of the pilot will help to determine the actual duration of the two test days. It Is likely that the duration of these tests will be shorter than the 12-hour period chosen for the pilot. Total amount of time spent on the actual study will be a maximum of 25 hours (1-hour screening + 2 x 12 hours). In contrast to the pilot, the subjects do not need to undergo additional vena punctures for tracer clearance . Total amount of blood drawn during the study will be maximal 436 ml. The same risks are attributed to the actual study as for the pilot.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Healthy male
- Age 18+
- BMI 18-25 kg/m2

Exclusion criteria

Dyslipidemia (hypertriglyceridemia)
Any acute or chronic illness that would interfere with the subjects safety and ability to comply with protocol requirements

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	15-03-2018
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	13-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2018
Application type:	Amendment
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

ID: 25246
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59693.018.16
OMON	NL-OMON25246