Effect of N3-polyunsaturated fatty acids on peripheral insulin sensitivity.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19945

Source
NTR

Brief title
Fish Oil and Insulin Resistance

Health condition

Trans parenteral nutrition
nutirtion
Insulin resistance

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Endocrinology and Metabolism
Source(s) of monetary or material Support: Academic Medical Center (AMC), Department of Endocrinology and Metabolism

Intervention

Outcome measures

Primary outcome

To study the acute effect of iv SMOFlipid® on peripheral glucose uptake in healthy humans.

Secondary outcome

To study the accumulation of FA metabolites and components of the insulin signaling pathway after infusion of SMOFlipid®.

Study description

Background summary

Fatty acids (FA) are no longer considered solely as a source of energy but also as potent regulators of intermediary metabolism. N3-poly unsaturated fatty acids (N3-PUFA) have been shown to be associated with a lower prevalence of cardiovascular diseases. FA are also involved in obesity induced insulin resistance and DM2. Saturated fatty acids are known for their negative interference on insulin stimulated glucose uptake in peripheral tissues. We recently studied the effect of two different intravenous lipid emulsions containing a mixture of MUFA, PUFA and saturated fatty acids on insulin sensitivity (MEC 05-295) and found insulin resistance but no difference between the two different lipid emulsions. Lipid emulsions for parenteral nutrition containing fish oil are now available. SMOFlipid emulsion is commercially available and based on 30% soy-bean oil, 30% medium chain triglycerides (MCT), 25% olive oil and 15% fish oil. We hypothesize that SMOFlipid® has a less profound effect on insulin sensitivity compared to the two earlier studied lipid emulsions.

Study objective

1. SMOFlipid® decreases peripheral insulin sensitivity to a lesser extent compared to the other lipid emulsions, Intralipid® and Clinoleic®, due to the lower n6/n3 ratio and the higher MCT concentration in the SMOFlipid emulsion;

2. SMOFlipid®, rich in specific N3-PUFA and MCT, affects not only the serum fatty acid composition but also the concentrations of bioactive lipids within skeletal muscle.

Study design

Every participant will serve as his own control and study days will be performed in random assignment. Both study days for one individual will be scheduled at least two weeks apart.

Intervention

Hyperinsulinemic euglycemic clamp with stable isotopes and concomitant infusion of a fish oil containing lipid emulsion, SMOFlipid®, on one occasion, and control saline infusion on the other occasion. Infusion will take 6 hours. FFA levels will be clamped at approximately 0.5 mmol/L. At the end of both clamps a muscle biopsy from the musculus vastus lateralis will be performed. Each participant will serve as its own control. Studies will be performed in

balanced assignment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male;

2. BMI 20-25 kg/m2;

3. Stable weight during 3 months before participation and during participation;

4. Normal physical activity with at most 2 times per week sport activities;

5. Age 18-30;

6. Non-smoking;

7. Caucasian.

Exclusion criteria

1. Hypersensitivity to fish-, egg-, soya- or peanut protein;

2. Any medical condition or use of medication;

3. DM type II in first degree relatives;

4. Participation in other medical trial during the last 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34627
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2162
NTR-old	NTR2286
CCMO	NL30857.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34627

Study results

Summary results
N/A