The effect of dietary phytosphingosine on insulin resistance and cholesterol levels in patients with the metabolic syndrome

No registrations found.

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

Summary

ID

NL-OMON23195

Source
Nationaal Trial Register

Brief title
N/A

Health condition

diabetes mellitus
metabolic syndrome
obesitas

Intervention

Outcome measures

Primary outcome

• Glucose metabolism: HOMA-IR, HOMA-β
K-value by IVGTT

• Plasma concentrations: Total cholesterol (TC), HDL-C-cholesterol (HDL-C),

LDL-C-cholesterol (LDL-C), Triglycerides
Glucose, insulin

Secondary outcome

• Anthropometric:

Weight, height, waist and hip circumference, BIA

• Plasma concentrations:

ASAT, ALAT, gamma-GT, LDH, alkaline phosphatase
fibrinogen, CRP

Study description

Background summary

Background:

treatment with phytosphingosine leads to improvement in cholesterol spectrum and insulin resistance in animal models

Objective:

• To examine if dietary Phytosphingosines improve insulin sensitivity in male patients with the metabolic syndrome.

• To examine if dietary Phytosphingosines improve blood cholesterol levels in male patients with metabolic syndrome.

• To examine the safety and possible side effects of dietary Phytosphingosines

Study Design:

Double blind randomized cross-over placebo controlled intervention study

Planned Sample:

10 patients

Drugs and Dosages:

Phytosphingosine, twice a day 0.5 grams for 28 days

Placebo, twice a day for 28 days

Main Parameters:

• Anthropometric: Weight, height, waist and hip circumference, BIA

• Glucose metabolism: HOMA-IR, HOMA-β
K-value by IVGTT

• Plasma concentrations: Total cholesterol (TC), HDL-C-cholesterol (HDL-C),
LDL-C-cholesterol (LDL-C), Triglycerides
Glucose, insulin
ASAT, ALAT, gamma-GT, LDH, alkaline phosphatase
fibrinogen, CRP

Study objective

Phytosphingosine decreases cholesterol levels and improves insulin sensitivity

Study design

Before and after both 4 week interventions

Intervention

- Phytosphingosine, twice a day 0.5 grams for 28 days

- Placebo, twice a day for 28 days

Contacts

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Eligibility criteria

Inclusion criteria

1. Male volunteers

2. Age > 18 years and < 70 years

3. BMI > 27 kg/m2 and < 40 kg/m2

4. Central obesity (waist circumference >94 centimetres)

5. Fasting serum glucose > 5.6 mmol/L

6. Fasting serum insulin >15 mU/L

7. TG ≥ 1.7 mmol/L or HDL-C ≤ 1.03 mmol/L

Exclusion criteria

1. Any significant chronic disease

2. Renal, hepatic or another endocrine disease

3. Use of medication known to influence lipolysis and/or glucose metabolism

4. Difficulties to insert an intravenous catheter

5. Smoking

6. Recent blood donation (within the last 3 months)

7. Recent participation in other research projects (within the last 3 months), participation in 2 or more projects in one year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-04-2008
Application type:	First submission

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
NTR-new	NL1242
NTR-old	NTR1287
Other	: P06-131
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A