Effects of fenofibrate and fish oil on gene expression and metabolic changes in obese subjects

Published: 01-03-2007
Last updated: 14-05-2024

The objective of this study is to compare in obese subjects the effects of fenofibrate (200 mg/day) with those of fish oil (7.2 g/day) on expression of PPARα related genes and metabolic parameters.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30822

Source
ToetsingOnline

Brief title
Effects of fenofibrate and fish oil in obese subjects

Condition

- Metabolism disorders NEC

Synonym
disturbed fat and glucose metabolism, Metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Wageningen Center for Food Sciences,Wageningen Centre for Food Sciences (WCFS)

Intervention

Keyword: fenofibrate, fish oil, metabolic syndrome, PPAR alpha

Outcome measures

Primary outcome

Expression of PPARα related genes, markers of insulin resistance, serum lipid

and lipoprotein profile and markers of inflammation.

Secondary outcome

not applicable

Study description

Background summary

The prevalence of the metabolic syndrome is strongly increasing in developed countries. Activation of PPARα may have a beneficial effect on several metabolic processes that are disturbed in subjects with the metabolic syndrome. PPARα can be activated by fibrates (a drug), but it would be helpful for many people if these effects could also be achieved with a dietary component. In this respect, fish oil deserves attention, as many in vitro and animal studies have suggested that the highly polyunsaturated fatty acids from fish oil are potent PPARα agonists. However, fibrates have never been compared side-by-side with fish oil.

Study objective

The objective of this study is to compare in obese subjects the effects of fenofibrate (200 mg/day) with those of fish oil (7.2 g/day) on expression of PPARα related genes and metabolic parameters.

Study design

Randomised, double blind, placebo controlled cross over design. The duration of the experimental periods will be 6 weeks, separated by wash out periods of 2 weeks. Subjects will consume in random order a) 200 mg fenofibrate together with 7.2 g of sunflower oil placebo and b) 7.2 g fish oil together with 200 mg placebo cellulose placebo and c) 200 mg cellulose placebo together with 7.2 g

sunflower oil placebo.

Intervention

Subjects will consume in random order a) 200 mg fenofibrate together with 7.2 g of sunflower oil placebo and b) 7.2 g fish oil together with 200 mg placebo cellulose placebo and c) 200 mg cellulose placebo together with 7.2 g sunflower oil placebo. A capsule of fenofibrate or cellulose (100 mg) together with 4 capsules of fish oil or sunflower oil (a 900 mg) have to be taken twice daily, half an hour before breakfast and half an hour before dinner with a glass of water.

Study burden and risks

Total time investment for the subjects will be 480 minutes.
Venipuncture and biopsies may cause bruises or a hematoma.
Although risks are minimal, the most common causally related adverse effects of fibrates are digestive, musculoskeletal and dermatologic of nature.
Fish oil supplements, although generally well tolerated, could have as adverse side effect a mild gastrointestinal discomfort and a fishy smelling breath and/or urine.

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

Body Mass Index > 27 kg/mw
or waist circumference > 88 cm (women) or >102 cm (men)

Exclusion criteria

- BMI < 27 kg/m2 and waistcircumference <88 cm (women) or <102 cm (men)
- Use of PPARα agonists and / or n-3 / n-6 fatty acid supplements
- Serum cholesterol > 8 mmol/l
- Use of medication that can interact with fenofibrate (study medication), including: HMGCoA reductase inhibitors (statins, eg. lovastatin, pravastatin, simvastatin), anticoagulants (eg. acenocoumarol, phenindione, warfarin)
- Hypersensitivity to (feno)fibrate products
- Active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, CVA)
- Pre-existing gallbladder disease
- Diabetes mellitus and anti-diabetic medication (e.g. PPARγ agonists)
- Familial hypercholesterolemia
- Severe medical conditions that might interfere with the study such as epilepsy, asthma, COPD, inflammatory bowel diseases and rheumatoid arthritis.
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Impairment of renal function, as evidenced by increased serum creatinine >150 mmol/L
- Hepatic diseases as manifested by ALT, AST, GGT, total bilirubin or ALP > 2 times the upper limit of normal
- Abuse of drugs and/or alcohol
- Pregnant or breast-feeding women
- Participation in another biomedical study within 1 month prior to the start of this study
- Having donated blood (as blood donor) within 1 month prior to start of this study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2007
Enrollment:	30
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Lipanthyl, Fournier Pharmaceuticals
Generic name:	micronised fenofibrate

Ethics review

Approved WMO Date:	01-03-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	26-03-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2006-005743-28-NL
CCMO	NL14699.068.06