A randomized, double blind, cross-over trial to study the effects of adding bezafibrate to standard lipid lowering therapy on postprandial lipids in patients with Familial Dysbetalipoproteinemia

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To evaluate the difference in the post fat load non HDL after an oral fatload between bezafibrate and placebo in patients with FD using standard lipid-lowering therapy

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

Summary

ID

NL-OMON43954

Source
ToetsingOnline

Brief title
EFFECT-FD

Condition

- Lipid metabolism disorders

Synonym
Familial Dysbetalipoproteinemia, Fredrickson Type III hyperlipoproteinemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting vrienden van het UMC Utrecht

Intervention

Keyword: cholesterol, familial dysbetalipoproteinemia (FD), fibrate, post-prandial

Outcome measures

Primary outcome

The main study parameter is the difference in post fatload non-HDL-C

(pre-fatload minus post-fatload) between bezafibrate and placebo.

Secondary outcome

Difference in the post fat load TC, HDL-C, LDL-C, TG, apoB, CRP, glucose and

insulin after an oral fatload between bezafibrate and placebo.

Difference in fasting non-HDL-C, TC, HDL-C, LDL-C, TG, apoB, CRP, glucose and

insulin between bezafibrate and placebo.

Difference in fasting and post fat load adipo(cyto)kines and markers of

inflammation between bezafibrate and placebo.

Safety of bezafibrate.

Study description

Background summary

Patients with familial dysbetalipoproteinemia (FD) have increased

triglycerides, non-high-density lipoprotein cholesterol (non-HDL-C), beta-VLDL, premature atherosclerosis and cardiovascular disease. They also have a delayed post-prandial triglyceride and chylomicron remnant (CM) clearance.
Post-prandial hypertriglyceridemia is associated with increased vascular risk. Although combination therapy with statin and fibrate is recommended in the treatment of patients with FD, the evidence is old and based on small numbers of patients. Furthermore no information is available about the postprandial effects of adding a fibrate to standard lipid lowering therapy in FD patients.

Study objective

To evaluate the difference in the post fat load non HDL after an oral fatload between bezafibrate and placebo in patients with FD using standard lipid-lowering therapy

Study design

Randomised, double blind, cross-over trial. It consist of 2 treatment periods in which patients receive Bezafibrate and placebo in a randomised order. Between treatment periods is a 2 week cross-over period. Before treatment period 1 and at the end of the 2 treatment periods patients visit the hospital for an oral fatload. Before an after the fatload blood samples are collected through an intravenous catheter. Patients have to stay untill 6 hours after the fatload and receive a meal at the end. Before the visits to the hospital people have to fast for at least 8 hours (meaning that they cannot eat or drink anything, except water). The study lasts 18 weeks in total.

Intervention

Bezafibrate retard 400 mg per day

Study burden and risks

Risk: low but known and unknown side effects of Bezafibrate can occur. Minimal risk concerning venapunctions are pain, hematoma or infection of injection site.
Burden: patients are asked to keep a stable diet an alcohol consumption. They have to visit the UMCU 4 times in total. Before all the visits patients have to fast for 8 hours. Three of the visits include ingestion of an oral fatload (unsweetened cream). Patients might not like the taste of the cream. The 3 visits can last up to 7 hours. The screenings visit lasts 60 minutes.

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

- age > 18 years
- genetic confirmation of E2 homozygote- or FD dominant genotype in combination with a clinical diagnosis of Familial Dysbetalipoproteinemia
- women are postmenopausal
- any lipid lowering treatment including lifestyle

Exclusion criteria

- fibrate use
- sensitivity/allergy to fibrates
- history of galbladder disease

- history of rhabdomyolysis
- eGFR <60 ml/min/1.73m2
- Impaired liver function
- CK > 3*ULN

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bezalip retard
Generic name:	Bezafibrate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	08-04-2015

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-05-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2014-000524-26-NL
CCMO	NL52026.041.15