# EFFECT-FD: Effect of adding bezaFibrate to standard lipid lowering therapy on non-Fasting CholesTerol in patients with Familial Dysbetalipoproteinemia

Gepubliceerd: 12-06-2015 Laatst bijgewerkt: 18-08-2022

Bezafibrate will significantly reduce post-prandial non-HDL cholesterol in patients with Familial Dysbetalipoproteinemia compared to placebo.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29530

**Bron**
NTR

**Verkorte titel**
EFFECT-FD

**Aandoening**

Familial Dysbetalipoproteinemia
Familiaire Dysbetalipoproteinemie (dutch)

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht
**Overige ondersteuning:** Friends of UMC Utrecht foundation

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Post fatload non-HDL cholesterol.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Randomized, double blind, cross-over trial in 20 patients with Familial Dysbetalipoproteinemia using standard lipid-lowering therapy. The study consists of two 6-week treatment periods, with a 2 week crossover periode in between, in which patients receive Bezafibrate 400mg daily or placebo in a random order. Primary endpoint is difference between bezafibrate and placebo in postprandial non-HDL cholesterol after an oral fatload. Other endpoints are: total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, apoB, CRP, glucose, insulin, adipocytokines and markers of inflammation.

### Doel van het onderzoek

Bezafibrate will significantly reduce post-prandial non-HDL cholesterol in patients with Familial
Dysbetalipoproteinemia compared to placebo.

### Onderzoeksopzet

Difference between Bezafibrate and placebo in post fatload non-HDL-C after a treatment period of 6 weeks.

### Onderzoeksproduct en/of interventie

Bezafibrate 400mg, tablet, once daily for 6 weeks.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Presence of a genetically confirmed apolipoprotein E2 homozygote genotype or an autosomal dominant FD genotype in combination with (at least) one of the following clinical characteristics:

o (History of) presence of xanthoma;

o ApoB/TC ratio <0.15 or;

o Use of lipid-lowering medication.

2. Age >18 years (on the day of signing informed consent). Both males and females will be included.

3. Women are postmenopausal and not receiving hormone therapy.

4. Any type of lipid lowering treatment, including lifestyle.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

o Use of any type of fibrate (including but not limited to gemfibrozil, bezafibrate, fenofibrate and ciprofibrate);

o Intolerance, known allergy or hypersensitivity to fibrate or any component of the medication;

o Unable to drink oral fatload;

o History of cholelithiasis or other biliary diseases;

o History of rhabdomyolysis;

o History of organ transplantation and/or immunosuppressive medication;

o Uncontrolled diabetes mellitus: HbA1c >69 mmol/mol;

o Untreated (sub)clinical hypothyroidism: defined as TSH ¡Ý5.0 mcIU/mL;

o Impaired renal function (estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m2 based on MDRD equation at the screening visit), need of hemodialysis or other clinically significant renal disease;

o Active liver disease or impaired liver function (AST/ALT >1.5x ULN);

o Creatinine kinase (CK) >3 x ULN;

o Poorly controlled blood pressure with systolic blood pressure >180mmHg or diastolic blood pressure >100mmHg at the screening visit;

o Active malignancy (¡Ü 2 year prior to informed consent);

o Human Immunodeficiency Virus (HIV) or AIDS;

o Celiac disease or other disorder associated with significant intestinal malabsorption;

o Alcohol abuse/excessive alcohol use, defined as >14 alcoholic consumptions per week.

o Use of anti-tuberculosis medication;

o Use of anti-epileptics;

o Use of oral anticoagulants;

o Use of monoamine oxidase (MAO) inhibitors (antidepressant);

o Use of cytochrome P450 3A4 (CYP3A4) inhibitors: oral antimycotics (fluconazol, itraconazol,

ketoconazole, voriconazol, posaconazol), ciclosporin, grapefruit juice, mycines (azithromycin, clarithromycin, erythromycin), diltiazem, verapamil and amiodaron;

o Galactose-intolerance, Lapp-lactose deficiency or glucose-galactose malabsorption.

o Current participation or participation in a study with an investigational compound or device within 30 days of signing informed consent.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-07-2015 |
| Aantal proefpersonen: | 20 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 12-06-2015 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5095 |
| NTR-old | NTR5227 |
| Ander register | 2014-000524-26 : EudraCT number |

# Resultaten