A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant

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Primary: • To evaluate whether long-term treatment with bempedoic acid 180 mg/day versus placebo reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease (CVD) who are statin...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON53050

Source
ToetsingOnline

Brief title
CLEAR Outcomes

Condition

- Heart failures

Synonym
cardiovascular disease, heart and blood vessel disease

Research involving
Human

Sponsors and support

Primary sponsor: Esperion THerapeutics Inc.,
Source(s) of monetary or material Support: the pharmaceutical industry

Intervention

Keyword: Bempedoic acid, Cardiovascular, Efficacy, Safety

Outcome measures

Primary outcome

Time to first occurrence of a confirmed MACE. Mace is defined as CV death,

nonfatal MI, nonfatal stroke, or coronary revascularization

Secondary outcome

Key secondary efficacy time-to-event endpoints:

• Time to first occurrence of the composite endpoint of CV death,

nonfatal MI, or nonfatal stroke

• Time to first occurrence of (fatal + nonfatal) MI

• Time to first occurrence of coronary revascularization

• Time to first occurrence of (fatal + nonfatal) stroke

• Time to CV death

• Time to all-cause mortality

Secondary efficacy time-to-event endpoints:

• Time to first occurrence of the composite endpoint of all-cause

mortality, nonfatal MI, nonfatal stroke, or coronary revascularization

• Time to first occurrence of nonfatal MI

• Time to fatal MI

• Time to first occurrence of nonfatal stroke

• Time to fatal stroke

• Time to first occurrence of (fatal + nonfatal) hemorrhagic stroke

• Time to first occurrence of (fatal + nonfatal) nonhemorrhagic stroke

• Time to hospitalization for unstable angina

• Time to first occurrence of new-onset type 2 diabetes mellitus defined by one or more of the following criteria according to the current American Diabetes Association (ADA) guidelines (ADA, 2014):

1. Fasting plasma glucose >=126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours;* or

2. Two-hour post-prandial glucose >=200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test as defined in the ADA guidelines;* or

3. HbA1C measurement >=6.5% (48 mmol/mol);* or

4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose >=200 mg/dL (11.1 mmol/L).

*Note: In the absence of unequivocal hyperglycemia, diagnosis requires 2 abnormal test results from the same sample or in the 2 separate test results.

Secondary efficacy lipid and biomarker endpoints:

• Percent change from baseline to Month 6 in LDL-C

• Percent change from baseline to Month 6 in hs-CRP

• Absolute change from baseline to Month 12 in HbA1C in patients in the inadequately controlled diabetes efficacy population (patients with type

2 diabetes mellitus and an HbA1C of 7% or greater at baseline)

Timepoint(s) of evaluation of this end point:

Time to first occurrence of composite endpoint of all-cause mortality,

nonfatal MI, nonfatal stroke, or coronary revascularization.

Safety Endpoints:

• AEs (including muscle-related AEs, new-onset or worsening type 2

diabetes mellitus, and neurocognitive AEs), heart rate, blood pressure

(BP), and clinical laboratory measures

• Change from baseline in glycosylated hemoglobin, Type A1C (HbA1C)

and fasting serum glucose at Months 3, 12, and end-of-study.

Study description

Background summary

Bempedoic acid (ETC-1002) is an oral, first-in class, small molecule designed to lower low-density lipoprotein cholesterol (LDL-C). It inhibits adenosine triphosphate-citrate lyase (ACL), an enzyme upstream of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase in the cholesterol biosynthesis pathway. Bempedoic acid, like statins, inhibits cholesterol synthesis and up-regulates LDL-C receptors. However, unlike statins, bempedoic acid does not inhibit cholesterol synthesis in muscle tissue, therefore it is anticipated that negative muscle-related adverse effects associated with statin use may be avoided by use of bempedoic acid.
Patients who are statin intolerant have an unmet medical need for therapeutic options to lower LDL-C and reduce their risk of cardiovascular disease (CVD). Recent mechanistic and clinical data suggest that bempedoic acid may meet this medical need with a once-daily, nonstatin alternative. This Phase 3 study is being conducted as a part of a comprehensive Phase 3 program to determine whether bempedoic acid will reduce the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, CVD who are unable to

tolerate statins.

Study objective

Primary:
• To evaluate whether long-term treatment with bempedoic acid 180 mg/day versus placebo reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease (CVD) who are statin intolerant. This will be assessed with a composite primary efficacy endpoint that includes time to first occurrence of cardiovascular (CV) death, nonfatal myocardial infarction (MI), nonfatal stroke, or coronary revascularization

Secondary:
• To evaluate whether long-term treatment with bempedoic acid 180 mg/day versus placebo reduces the risk of other clinical endpoints of CV morbidity and mortality and all-cause mortality.
• To evaluate the effect of long-term treatment with bempedoic acid 180 mg/day versus placebo on LDL-C and high-sensitivity C-reactive protein (hsCRP).
• To evaluate the long-term safety and tolerability of bempedoic acid 180 mg/day compared to placebo.
•To evaluate the 12-month efficacy of treatment with bempedoic acid 180 mg/day versus placebo on absolute change in hemoglobin A1c (HbA1C) in the inadequately controlled diabetes efficacy population (patients with type 2 diabetes mellitus and having an HbA1C of 7% or greater at baseline)
•To evaluate whether long-term treatment with bempedoic acid 180 mg/day versus placebo reduces the risk of new-onset diabetes.

Study design

This is a Phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel group study. Screening (Visit S1) will occur approximately 5 weeks prior to Day 1 (Visit T1), but can be extended for an additional 5 weeks if needed to adjust background medical therapy or for other reasons. All eligible patients will return at Week -4 (Visit S2) to initiate a 4-week Run-in Period once daily that will include assessment of tolerability and investigational medicinal product (IMP) adherence. On Day 1 (Visit T1), approximately 12,604 eligible patients will be randomized 1:1 to receive either double-blind bempedoic acid 180 mg (n = 6,302) or placebo (n = 6,302) once daily. Randomized patients will return for clinic visits at Month 1 (Visit T2), Month 3 (Visit T3), and Month 6 (Visit T4). Following Month 6, patients will be contacted every 3 months (alternating with a phone visit and a clinic visit) for the remainder of the study.

Intervention

Patients will be randomized 1:1 to receive either double-blind bempedoic acid 180 mg or placebo once daily. The estimated enrollment period is approximately 30 months. It is estimated the mean treatment duration will be approximately 42 months (3.5 years), with all patients remaining in the study for a minimum of 24 months (2 years) and some patients remaining in the study for up to approximately 69.5 months (5.75 years). The study will continue until all 3 criteria for study end described in Section 6.5 of the protocol have been met. Depending on the rates of accumulating endpoints in this study, the study duration may be shorter or longer. The estimated overall duration of the study (first patient first visit to last patient last visit) is approximately 69.5 months (5.75 years).

Study burden and risks

One of the reasons for this study is to learn more about the possible side effects of the study drug. As bempedoic acid is an investigational drug, not all side effects are known at this time, and there is a risk that rare or previously unknown side effects may occur. Patient may have side effects from the study drug or from the tests or procedures used in this study. Side effects usually vary from person to person, and can range from mild to very serious.
To date, approximately 700 patients with increased cholesterol levels have received at least one dose of bempedoic acid, with doses ranging from 2.5 mg to 240 mg for up to 12 weeks. Generally, the number of side-effects reported by patients receiving bempedoic acid was similar to the number of side-effects reported by patients receiving placebo.
There is no guarantee that the subject will receive any medical benefit from taking part in this study. His/her health could improve, it could stay the same, or it could get worse. However, the information we learn about the study drug may help other people with cardiovascular disease in the future.

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

1. Provision of signed informed consent prior to any study-specific procedure.
2. Patient reported SI due to an adverse safety effect that started or increased during statin therapy and resolved or improved when statin therapy was discontinued resulting in an inability to tolerate:
• 2 or more statins at any dose, or
• 1 statin at any dose and unwilling to attempt a second statin or advised by a physician to not attempt a second statin. Please note that patients currently tolerating very low dose statin
therapy (an average daily dose of rosuvastatin <5 mg, atorvastatin <10 mg, simvastatin <10 mg, lovastatin <20 mg, pravastatin <40 mg,fluvastatin <40 mg, or pitavastatin <2 mg) are considered to be intolerant to that low dose statin. Patients may continue taking very low dose statin therapy throughout the study provided that it is stable (used for at least 4 weeks prior to screening) and well tolerated., 3. Written confirmation by both patient and investigator that the patient is statin intolerant as defined above and aware of the benefit of statin use to reduce the risk of MACE including death, and also aware that many other patients who are unable to tolerate a statin are able to tolerate a different statin or dose.
4. Age >=18 years or legal age of major
4. Age >=18 years or legal age of majority based on regional law, whichever is greater, and <=85 years at Week -5 (Visit S1).
5. Men and nonpregnant, nonlactating women. Women must be one of the following:
• Naturally postmenopausal defined as >=1 year without menses and:
o >=55 years, or
o <55 years with follicle-stimulating hormone (FSH) >=40.0 IU/L, or
• Surgically sterile including hysterectomy, bilateral oophorectomy, and/or tubal ligation, or
• Women of childbearing potential willing to use an acceptable method(s) of

birth control during the study and for 90 days after the end of treatment including:
o oral, topical, injectable, or implantable birth control medications,
o placement of an intrauterine device with or without hormones,
o barrier methods including condom or occlusive cap with spermicidal foam or spermicidal jelly,
o vasectomized male partner who is the sole partner for this patient,
o true abstinence that is in line with the preferred and usual lifestyle of the patient (periodic abstinence [eg, calendar, ovulation, symptothermal, postovulation methods], declaration of abstinence for the duration of the study or withdrawal are not acceptable methods of
true abstinence). There are no protocol-specific birth control requirements for men with partners who are able to become pregnant.
6. Fasting LDL-C >=100 mg/dL (2.6 mmol/L) at Week -5 (Visit S1) while taking stable (4 weeks prior to Visit S1) and optimized background LDLC- lowering therapies that may include very low dose statin (see definition above), ezetimibe, niacin, bile acid resins, fibrates, and/or proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors.
7. History of, or at high risk for, CVD including documented evidence of one or more of the following:
a. Documented history of CVD (ie, secondary prevention)
• Coronary artery disease, defined by:
o MI (either ST-elevation MI or non-ST-elevation MI) occurring greater than 90 days prior to screening, or
o Percutaneous coronary or surgical coronary revascularization, occurring greater than 90 days prior to screening, or
o Angiographic stenosis of >50% in a least 1 major coronary artery (native or graft vessel), as documented by selective coronary angiography or computed tomography angiography (CTA), or
• Symptomatic peripheral arterial disease (PAD) , defined by:
o Peripheral vascular disease with symptoms of claudication or resting limb ischemia with either ankle brachial index <0.9 or angiogram (including CTA) showing >=50% stenosis, (ankle brachial index will be measured after a period of rest and with the patient in the supine position using a Doppler device) or Peripheral arterial revascularization (surgical or percutaneous), occurring greater than 90 days prior to screening, or
o Abdominal aortic aneurysm confirmed by imaging or aortic aneurysm repair, occurring greater than 90 days prior to screening, or
o Lower extremity amputation due to peripheral vascular disease, occurring greater than 90 days prior to screening, or
• Cerebrovascular atherosclerotic disease defined by:
o Ischemic stroke occurring greater than 90 days prior to screening, or
o Carotid endarterectomy, carotid stenting, or more than 70% stenosis in a carotid artery determined by carotid ultrasound or angiogram occurring greater than 90 days prior to screening, or
b High risk for a CVD event (ie, high-risk primary prevention):
o Reynolds Risk score >30% or a SCORE Risk score >7.5% over 10 years, or

o Coronary artery calcium score >400 Agatston units (AU) at any time in the past, or
o Patients with type 1 or type 2 diabetes, aged >65 years (women) or >60 years (men)

Exclusion criteria

Patients who meet any of the following criteria will not be eligible to participate:
1. Total fasting TG >500 mg/dL (5.6 mmol/L) at Week -5 (Visit S1).
Note: A single repeat of TG may be completed prior to initiation of the single-blind Run-in Period. For those patients who have a repeat TG, the repeat value will be used to determine eligibility.
2. Renal dysfunction or a glomerulonephropathy defined as either nephritic or nephrotic syndrome, including estimated glomerular filtration rate (eGFR; using central laboratory determined Modification of Diet in Renal Disease [MDRD] formula) <30 mL/min/1.73 m2 at Week -5 (Visit S1).
Note: A single repeat of eGFR may be completed prior to randomization. For those patients who have a repeat eGFR, the repeat value will be used to determine eligibility.
3. Forms of CVD that include any of the following:
a. Recent (within 90 days prior to or during screening) acute CVD events including, but not only, transient ischemic attack (TIA), MI, coronary revascularization, peripheral arterial revascularization, ischemic stroke, carotid endarterectomy, carotid stenting.
b. Recent (within 90 days of screening) unstable or symptomatic cardiac arrhythmia (including any associated medication changes). Patients with stable well-controlled atrial arrhythmias will be allowed to participate in the study.
c. Patients with implantable pacemakers or automatic implantable cardioverter defibrillators may be considered if deemed by the investigator to be stable for greater than 90 days prior to screening,
d. New York Heart Association (NYHA) Functional Classification Class IV heart failure,
e. Uncontrolled hypertension, defined as mean sitting systolic blood pressure (SBP) >=180 mmHg and/or diastolic blood pressure (DBP) >=110 mmHg,
f. Planned coronary revascularization (patient may rescreen 3 months post-procedure).
Note: At the discretion of the investigator, BP medications can be adjusted and/or additional assessment of BP may be completed prior to randomization, with the repeat assessment value used to determine eligibility. Alternatively, patients can be rescreened if BP status has changed.
4. HbA1C >=10% at Week -5 (Visit S1).
5. Uncontrolled hypothyroidism, including thyroid-stimulating hormone (TSH) >1.5 × the upper limit of normal (ULN) at Week -5 (Visit S1). Note: At the discretion of the investigator, thyroid replacement therapy can be adjusted

and/or additional measurement of TSH may be completed prior to randomization, with the repeat TSH value used to determine eligibility.
6. Liver disease or dysfunction, including:
a) Positive serology for hepatitis B surface antigen (HBsAg) and/or hepatitis C antibodies (HCV-ABVivi) at Week -4 (Visit S2), or
b) Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) >=2.0 × ULN at Week -5 (Visit S1).
Note: At the discretion of the investigator, a single repeat of ALT and/or AST may be completed prior to randomization. For those patients who have a repeat ALT and/or AST, the repeat value will be used to determine eligibility. Also, if test for Hepatitis C antibody is positive, but optional reflexive test for Hepatitis C RNA is negative, patient can be enrolled.
7. Gastrointestinal conditions or procedures (including weight loss surgery; eg, Lap-Band® or gastric bypass) that may affect drug absorption.
8. Hematologic or coagulation disorders or a hemoglobin (Hgb) level <10 g/dL at Week -5 (Visit S1).
9. Active malignancy, including those requiring surgery, chemotherapy, and/or radiation in the past 5 years. Nonmetastatic basal or squamous cell carcinoma of the skin and cervical carcinoma in situ are allowed.
10. Unexplained creatine kinase (CK) >3 × ULN at Week -5 (Visit S1) (ie, not associated with recent trauma or physically strenuous activity). Patients with an explained CK elevation must have single repeat CK <=3 × ULN prior to randomization.
11. History within the last 2 years of drug, alcohol, amphetamine and derivatives, or cocaine abuse. Patients with amphetamine derivatives prescribed by and under the care of a health care practitioner can be enrolled after evaluation by the investigator.
12. Blood transfusion for any reason within 30 days prior to randomization.
13. Use of any experimental or investigational drugs within 30 days prior to screening or 5 half-lives, whichever is longer.
14. Randomization into another Phase 3 bempedoic acid clinical study.
15. Use of, or a plan to initiate, these prohibited therapies/supplements during the study:
• Mipomersen (must be stopped at least 6 months prior to Week -5 [Visit S1]), lomitapide or apheresis therapy (must be stopped at least 3 months prior to Week -5 [Visit S1]),
• Red yeast rice (must be stopped at least 2 weeks prior to Week -5 [Visit S1]),
• Statins are prohibited at average daily doses of rosuvastatin >=5 mg, atorvastatin >=10 mg, simvastatin >=10 mg, lovastatin >=20 mg, pravastatin >=40 mg, fluvastatin >=40 mg, or pitavastatin >=2 mg.
16. Planned initiation or dose adjustments of these allowed drugs less than 4 weeks prior to screening and during the clinical trial (stable use of these drugs is permitted):
• Statins are allowed only at average daily doses of rosuvastatin <5 mg, atorvastatin <10 mg, simvastatin <10 mg, lovastatin <20 mg, pravastatin <40 mg, fluvastatin <40 mg, or pitavastatin <2 mg,(must be stable at least 4 weeks

prior to Week -5 [Visit S1])
• Other lipid regulating drugs or supplements (must be stable at least 4 weeks prior to Week -5 [Visit S1])
• PCSK9 inhibitors (must be stable at least 12 weeks prior to Week -5 [Visit S1])
17. Lack of adherence (ie, less than 80% of planned doses) with IMP (single-blind placebo) during the Run-in Period.
18. Lack of tolerance with IMP (single-blind placebo) during the Run-in Period.
19. A medical or situational (ie, geographical) finding that in the investigator's opinion may compromise the patient's safety or ability to complete the study.
20. An employee or contractor of the facility conducting the study, or a family member of the Principal Investigator, Co-Investigator, or Sponsor.
21. Pregnant, breastfeeding, or intending to become pregnant within 90 days after study completion or last dose of IMP.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2017
Enrollment:	828
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Not applicable
Generic name:	Bempedoic acid

Ethics review

Approved WMO Date:	18-01-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-06-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-07-2017

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-10-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-01-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-02-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-03-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-08-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-08-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-11-2018
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-02-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-04-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-04-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-12-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-06-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	06-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	31-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2016-003485-11-NL
ClinicalTrials.gov	NCT02993406
CCMO	NL59585.056.16