A 52-Week, Phase 3, Randomized, Active Comparator and Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous SCH 900222 / MK-3222, Followed by an Optional Long Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-011)

Published: 03-04-2013
Last updated: 25-04-2024

Primary Trial ObjectivesBase Study1) Primary Efficacy Objective: To assess the efficacy of SCH 900222/MK-3222, hereafter referred to as MK-3222, compared to placebo in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cornification and dystrophic skin disorders
Study type	Interventional

Summary

ID

NL-OMON50707

Source
ToetsingOnline

Brief title
reSURFACE-11

Condition

- Cornification and dystrophic skin disorders

Synonym
plaque psoriases, psoriasis vulgaris

Research involving
Human

Sponsors and support

Primary sponsor: Sun Pharma Global FZE
Source(s) of monetary or material Support: Sun Pharma Global FZE

Intervention

Keyword: chronic plaque-psoriasis, MK-3222, phase 3, placebo controlled

Outcome measures

Primary outcome

Primary Efficacy Endpoint

• Proportion of subjects with PASI 75 response at Week 12

• Proportion of subjects with a PGA score of *clear* or *minimal* with at least

a 2 grade reduction from baseline at Week 12

See Protocol page 63

Secondary outcome

Key Secondary Efficacy Endpoints

• Proportion of subjects with PASI 75 response at Week 28

• Proportion of subjects with a PGA score of *clear* or *minimal* with at least

a 2 grade reduction from baseline at Week 28.

See Protocol page 63

Study description

Background summary

MK-3222 is being studied to see if it has any effect in treating diseases such as chronic plaque psoriasis. As of the most recent data review (April 25, 2012), approximately 516 healthy subjects, as well as those with chronic plaque psoriasis and Crohn*s Disease, have been exposed to MK-3222 either by intravenous (IV) injection (into the vein) or by subcutaneous (SC) injection (under the skin) up to a maximum dose of 10 mg/kg IV or 400 mg SC.

About 1050 people will be in the Base Study. If you are part of the Base Study only, you will be in the study for about 76 weeks (approximately 1 year and 6 months), which includes a screening period of up to 4 weeks, a treatment period of approximately 52 weeks, and a 20 week follow-up period.
If you are part of the Base Study and the Extension Study, you will be in the study for about 268 weeks (approximately 5 years and 2 months). In this case, the Base Study will last about 56 weeks (approximately 1 year and 1 month), which includes a screening period of up to 4 weeks and a treatment period of approximately 52 weeks. The Extension Study will last for about 212 weeks (approximately 4 years and 1 month); this part of the study will include a treatment period of 244 weeks and then continue in a 20 week follow-up period.

The purpose of the Base Study is to:
• test the safety/tolerability of the research study drug, SCH 900222/MK 3222 (which will be called MK-3222 in the rest of this consent form)
• test if MK-3222 is effective for treating moderate to severe chronic plaque psoriasis

The purpose of the Extension Study is to:
• test the long-term safety/tolerability of MK-3222

Study objective

Primary Trial Objectives

Base Study
1) Primary Efficacy Objective:
To assess the efficacy of SCH 900222/MK-3222, hereafter referred to as MK-3222, compared to placebo in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the proportion of subjects with at least 75% improvement in the Psoriasis Area and Severity Index from baseline (PASI 75 response) and the proportion of subjects with a Physician*s Global Assessment (PGA) score of *clear* or *minimal* with at least a 2 grade reduction from baseline at Week 12.

Primary Safety/Tolerability Objective: To assess the safety/tolerability of MK-3222 in subjects with moderate-to-severe chronic plaque psoriasis at Week 12.

Extension Study
Primary Objective: To assess long-term safety / tolerability of MK-3222 in subjects with moderate-to-severe chronic plaque psoriasis for a minimum of 4 years

2) Key Secondary Trial Objectives

Base Study:
1. To assess the efficacy of MK-3222 compared to etanercept in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the proportion of subjects with at least 75% improvement in the Psoriasis Area and Severity Index from baseline (PASI 75 response) and the proportion of subjects with a Physician*s Global Assessment (PGA) score of *clear* or *minimal* with at least a 2 grade reduction from baseline at Week 12
2. To assess the efficacy of MK-3222 compared to etanercept in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the proportion of subjects with at least 75% improvement in the Psoriasis Area and Severity Index (PASI 75 response) and the proportion of subjects with a Physician's Global Assessment (PGA) score of "clear" or "minimal" with at least a 2 grade reduction from baseline at Week 28.

Extension Study:
There are no key secondary objectives for the extension study.

Study design

A 52-Week, Phase 3, Randomized, , Active Comparator and Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous SCH 900222 / MK-3222, Followed by an Optional Long Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis

Base Study
Each subject who participates in the base study but opts not to continue in the long-term extension study will participate in the trial for approximately 76 weeks from the time the subject signs the Informed Consent Form (ICF) through the final contact. This consists of a screening phase of up to 4 weeks, an assigned treatment period of approximately 52 weeks, and a 20-week follow up period.
Eligible subjects who choose to enroll in the long-term extension study will participate for approximately 56 weeks in the base study. After a screening phase of up to 4 weeks and then the 52-week treatment period, the subjects will continue in the long-term safety extension study.

Extension Study

Each subject will participate for approximately 212 weeks from the time he or she enters the extension study through the final contact. Each subject will be receiving the assigned treatment for a minimum 192 weeks and then continue in a 20-week follow up period. Subjects will continue to receive treatment beyond 244 weeks until the product is commercially available in the subject*s local market or until December 2020 whichever comes first.

Intervention

Base Study

Part 1: Weeks 0 to 12, Visits 2-6
• Arm A: MK-3222 200 mg SC at Weeks 0 and 4 AND etanercept placebo twice weekly (n=300)
• Arm B: MK-3222 100 mg SC at Weeks 0 and 4 AND etanercept placebo twice weekly (n=300)
• Arm C: MK-3222 placebo SC at Weeks 0 and 4 AND etanercept placebo twice weekly (n=150)
• Arm D: MK-3222 placebo at Weeks 0 and 4 AND etanercept 50 mg SC twice weekly (n=300)

Part 2: Weeks 12 to 28 (Visits 7-9)
• Arms A and B will receive matching placebo of MK-3222 to maintain blinding at Week 12, and a SC dose of either MK-3222 200 mg (Arm A) or 100 mg (Arm B) at Week 16. Subjects will also receive etanercept placebo once weekly through Week 28.
• At Week 12, Arm C will be re-randomized to receive their first dose of MK-3222 200 mg or MK-3222 100 mg, and will receive additional doses of study medication according to their re-randomized treatment assignment at Week 16. Subjects will also receive etanercept placebo once weekly through Week 28.
• Arm D will continue with once-weekly doses of etanercept through Week 28. Subjects will receive matching placebo of MK-3222 to maintain blinding at Weeks 12 and 16.

Part 3: Weeks 28 to 52 (Visits 10-14)
• Arm A: Subjects with >= PASI 75 response at Week 28 (prior to their scheduled dose administration) will be re-randomized to either continue MK-3222 200 mg or receive MK-3222 100 mg administered at Weeks 28, 40 and 52. Subjects with >= PASI 50 response but < PASI 75 response (partial responders) will continue to receive MK-3222 200 mg every 12 weeks (dosing at Weeks 28, 40 and 52). Subjects with < PASI 50 response at Week 28 will be discontinued from study medication.
• Arm B: Subjects with >= PASI 75 response at Week 28 (prior to their scheduled dose administration) will continue to receive MK-3222 100 mg every 12 weeks (dosing at Weeks 28, 40 and 52). Subjects with >=PASI 50 response but < PASI 75 response (partial responders) will be re-randomized to either continue MK-3222 100 mg or receive MK-3222 200 mg administered at Weeks 28, 40 and 52. Subjects with < PASI 50 response at Week 28 will be discontinued from study medication.

• Arm C: Subjects will continue receiving additional doses of study medication at Weeks 28, 40 and 52 according to their re-randomized treatment assignment.
• Arm D: Subjects who achieve >=PASI 75 response at Week 28 (prior to any dose administration) will be discontinued from study medication. Subjects who do not achieve >=PASI 75 response (etanercept non-responders) at Week 28 will be crossed over to MK-3222 200 mg, receiving doses at Weeks 32, 36, and 48. Additional doses of MK-3222 placebo will be administered to maintain blinding.

Extension Study:

Subjects will receive MK-3222 200 mg or 100 mg every 12 weeks through Ext Week 244, depending on the treatment received at the time of completion of Part 3 of the base study (i.e. subjects will receive the same treatment in the extension study as what was received at the completion of the base study).

Study burden and risks

You may feel discomfort during some of these tests or may experience some inconveniences. Some may also have risks, which may include:

• Blood samples: drawing blood from your arm may cause pain, bruising, lightheadedness, and rarely, infection.
• Tuberculin Skin Test: A tuberculin skin test for tuberculosis (TB) involves the injection of a small amount of tuberculin fluid just under the skin in your forearm. You may have mild pain, bleeding and a change in skin color or bruising, and/or rarely, an infection from the needle stick. If you have a positive skin test, you may experience pain, itching, redness, firmness, and swelling at the site of the skin test.
• Blood pressure: An inflatable cuff will be placed on your arm. You may experience mild discomfort in your arm while the cuff is inflated.
• ECG: Small amount of liquid gel will be applied and sticky pads will be stuck to your chest, shoulders and hips and a machine will measure the electrical activity of your heart. We may need to clip small patches of your hair in these areas. These sticky pads or gel may cause some local irritation and the pads may be uncomfortable to remove.
• Everyone is exposed to radiation from sources in their normal living environment, such as sunlight and the small amounts of naturally occurring radioactive elements in our food (background radiation). If you need to have a chest X-ray, the amount of radiation that you will receive from this X-ray is about the same amount you would get in 10 days normally from all sources (natural and man-made). If you need to have a computerized tomography (CT) scan, you will be exposed to radiation in the form of X-rays. The amount of radiation exposure from the CT scan would be the equivalent of natural radiation exposure for 6 months to 2 years.

For MK 3222:

Side Effects in Healthy Volunteers:
There were 3 studies of MK-3222 in healthy subjects. The following side effects were reported in at least 2% of subjects in any of the three studies who are known to have received MK-3222: upper respiratory tract infection (cold like symptoms), headache, tiredness, painful menstrual period, injection site pain, injection site redness, nausea, hematoma (blood collection under the skin).
In addition to the side effects listed above, the reported separate events of Chikungunya virus infection, appendicitis and thoughts of suicide were considered to be serious adverse events and each was considered unlikely to be related to the study medication by the study doctor.
Side Effects in Patients with Crohn*s Disease:
In a study of patients with Crohn*s disease, the most commonly reported side effects occurring in more than 1 patient were headache, fatigue, lower abdominal pain, vomiting, dizziness, and nausea.
Side Effects in Patients with Psoriasis. These side effects were considered to be related to the study medication by the study doctor:
In 5 completed studies study of patients with psoriasis, the following side effects were reported in at least 2% of patients who are known to have received MK-3222: Alanine aminotransferase increased; Blood bilirubin increased; Aspartate aminotransferase increased (all are abnormal blood tests of the liver); Liver function test abnormal Lymphadenopathy (swollen lymph nodes), Arthralgia (joint pain), Musculoskeletal pain (muscle, bone, ligament, tendon pain), Asthenia (loss of energy); Fatigue Nasopharyngitis (head cold), Blood Chloride decreased, Nausea, Blood creatinine phosphokinase increased (abnormal blood test - protein related to muscle damage), Neck pain, Bronchitis, Pain in extremity, Conjunctivitis (pink eye), Paraesthesia (tingling), Convulsion (seizure), Paraesthesia oral (tingling in the mouth), Cough Pharyngitis streptococcal (strep throat), Diarrhea, Patelet count decreased; Thrombocytopenia (low number of platelets [cells involved in blood clotting]), Erysipelas (bacterial infection of the skin), Pneumonia (infection in the lungs), Gastroenteritis (inflammation of the stomach and intestines), Pruritus (itching), Headache, Pulpitis dental (inflammation inside a tooth), Hyperhidrosis (excessive sweating), Pyrexia (fever), Hypokalaemia (low potassium), Rhinitis (runny nose), Infected dermal cyst (infected pore in the skin), Subcutaneous abscess (pus pocket under the skin), Influenza (flu), Thrombophlebitis (clot in a vein and inflammation), Injection site pain (pain at the site of study drug administration), Upper respiratory tract infection (cold like symptoms), Libido decreased (decreased sexual desire), Vertigo (dizziness), Lymphadenopathy (swollen lymph nodes), Vulvovaginal mycotic infection (fungal infection of the vagina and vulva).

In addition to the side effects listed above for the Phase 1, 2 and 3 studies in patients with psoriasis, as of 5 July 2016, the following serious adverse events were reported in patients who are known to have taken tildrakizumab (MK-3222). These serious adverse events were considered to be related to the study medication by the study doctor.

Appendicitis (infection in the appendix), Hypertensive crisis (severely high blood pressure), Arthritis bacterial (infection of a joint caused by bacteria), Infected dermal cyst (infected pore in the skin), Benign biliary neoplasm (non-cancerous mass of the bile duct), Pneumonia - (Infections in lungs), Bladder transitional cell carcinoma (bladder cancer), Infectious colitis (infection in the large intestine), Bone tuberculosis (bacterial infection in the bone), Loss of consciousness, Carotid artery stenosis (narrowing of the carotid artery in the neck), Chronic cardiac failure, Lymphoedema (swelling due to blockage of the lymphatic system), Cellulitis (inflammation of the skin and tissue under it) - 3 cases reported, Melanoma, Malignant melanoma (skin cancer), Convulsion (seizure), Mesenteric artery thrombosis (clot in the artery of the intestines), Lung neoplasm malignant (abnormal growth of tissues in the lungs, characteristic of lung cancer), Diffuse large B-cell lymphoma (cancer of the lymph nodes), Psoriasis Epiglottitis (swelling of the epiglottis) - 2 cases reported, Staphylococcal infection (bacterial infection), Gastric cancer (cancer of the stomach), Ischaemic stroke; Cerebrovascular accident; Cerebral infarction (Stroke) - total 3 cases reported, Meningitis viral, Gastritis erosive (inflammation and wearing away of the stomach), Thyrotoxic crisis (severe overactivity of the thyroid gland), Rectal adenocarcinoma (a malignant tumor formed in the tissues of the rectum), Non-Hodgkin*s Lymphoma (cancer that starts in the lymphatic system), Gastroenteritis (inflammation of the stomach and intestines), Unstable angina (chest pain), Herpes zoster (shingles), Wound infection. Basal cell carcinoma (type of skin cancer that begins in the cells that produce new skin cells as old skin cells die), Myocarditis (inflammation in the middle layer of the heart wall), Peripheral arterial occlusive disease (a circulatory condition in which narrowed blood vessels reduce blood flow in the limbs), Thyroid cancer

In addition to the list of serious adverse events listed above, the following adverse reactions have been identified during post-approval use of tildrakizumab. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Abdominal pain upper, Myopathy, Actinomycosis (rare, infectious disease in which bacteria spread from one part of the body to another through body tissue), Neutropenia (abnormally low count of neutrophils in the blood), Atrial fibrillation (irregular heartbeat), Oral discomfort, Death - 1 case, Osteonecrosis (death of bone due to lack of blood supply), Dizziness, Pancreatic enzymes increased, Drug ineffective, Pruritus (itching), Generalized rash, Pruritus generalised, Guttate psoriasis (red, scaly, small, teardrop-shaped spots on the skin), Pyrexia (fever), Leukocytosis (high white blood cell count), Reactive gastropathy (gastritis; abnormality in the stomach caused by chemicals such as bile or alcohol, and characteristically has minimal inflammation), Leukopenia (low white blood cell count), Respiratory disorder, Lymphocytosis (higher-than-normal number of lymphocytes in the body), Suicidal ideation, Muscular weakness, Therapeutic response decreased, Myalgia (muscle pain), Walking aid user

Mycosis fungoides (also known as Alibert-Bazin syndrome; common form of cutaneous T-cell lymphoma)

While no specific side effects have been observed in animal studies and early human data have not established any particular side effects associated with MK-3222, there may be additional unknown risks in the treatment of human subjects with MK-3222. Because MK-3222 attaches to IL-23, a chemical messenger that is part of the immune system, the drug may affect the immune system with the potential risk of infection or cancer. As a large molecule protein drug, MK 3222 has the potential risk of an allergic reaction, which, if not treated promptly, could become life threatening. Symptoms of allergy can include a rash over all your body, shortness of breath, wheezing (trouble breathing), a fast pulse, sweating, or low blood pressure. If you think you are having an allergic reaction, you should immediately seek medical help. If significant new findings about MK 3222 become known to the Sponsor during your participation in this study, these findings will be provided to you and you may be asked to sign a new consent form.

For etanercept:

Etanercept may cause serious side effects, including:
1. Risk of infection
2. Risk of cancer

1. Risk of infection
Etanercept can lower the ability of your immune system to fight infections. Some people have serious infections while taking etanercept. These infections include TB and infections caused by viruses, fungi or bacteria that spread throughout the body. Some people have died from these infections.
Your doctor should test you for TB before starting etanercept.
Your doctor should monitor you closely for symptoms of TB during treatment with etanercept even if you tested negative for TB.
Your doctor should check you for symptoms of any type of infection before, during and after your treatment with etanercept.
You should not start taking etanercept if you have any kind of infection unless your doctor says it's okay.

2. Risk of cancer
There have been cases of unusual cancers in children and teenage patients who started using TNF-blocking agents at less than 18 years of age.
For children, teenagers and adults taking TNF-blocker medicines, including etanercept, the chances of getting lymphoma or other cancers may increase. People with rheumatoid arthritis or psoriasis, especially those with very active disease, may be more likely to get lymphoma.

The following side effects are those that have been seen in adult patients:

Very common (affects more than 1 in 10 subjects):
• Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections)
• Injection Site Reactions (including bleeding, bruising, redness, itching, pain, and swelling)
Reactions at the injection site are very common, but do not occur as often after the first month of treatment. Some patients have developed a reaction at an injection site that was used before.

Common (affects 1-10 subjects in 100):

• Allergic reactions
• Itching
• Fever
• Antibodies directed against normal tissue (autoantibody formation)

Uncommon (affects 1-10 subjects in 1000):

• Serious infections (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites)
• Low blood platelet count
• Skin cancer (excluding melanoma)
• Localized swelling of the skin (angioedema)
• Hives (elevated patches of red or pale skin that often itch)
• Eye inflammation
• Psoriasis (new or worsening)
• Rash
• Inflammation or scarring of the lungs
• Inflammation of the blood vessels affecting multiple organs

Rare (affects 1-10 subjects in 10,000):

• Lymphoma (a type of blood cancer)
• Melanoma (a type of skin cancer)
•Combined low platelet, red, and white blood cell count
•Tuberculosis
• Worsening congestive heart failure
•Seizures
• Low red blood cell count
• Low white blood cell count
• Low neutrophil (a type of white blood cell) count
• Elevated liver blood tests
• Skin rash
• Inflammation of the liver caused by the body*s own immune system (autoimmune hepatitis)
• Serious allergic reactions (including severe localized swelling of the skin and wheezing)

• Nervous system disorders (with severe muscle weakness and signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord)
• Lupus or lupus-like syndrome (symptoms may include persistent rash, fever, joint pain, and tiredness)
• Immune disorder that can affect the lungs, skin, and lymph nodes (sarcoidosis)

Very rare (affects less than 1 in 10,000 subjects):
• Failure of the bone marrow to produce crucial red blood cells

The following side effects have been reported by people who have taken etanercept, but the frequency cannot be estimated from the available data:
• Leukemia (cancer affecting the blood and bone marrow)
• Merkel cell carcinoma (a type of skin cancer)
• Excessive activation of white blood cells associated with inflammation (macrophage activation syndrome)

Specific Warnings and/or Instructions for Management of Specific AEs:
• Allergy: Do not use etanercept if you are allergic to etanercept or any other ingredients of etanercept. If you experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject etanercept, and contact your doctor immediately.
• Serious blood infection: Do not use etanercept if you have or are at risk of developing a serious blood infection called sepsis. If you are not sure, please contact your doctor.
• Infections: Do not use etanercept if you have an infection of any kind. If you are not sure, please talk to your doctor.
• Latex: The needle cover is made from latex (dry natural rubber). Contact your doctor before using etanercept if the needle cover will be handled by, or etanercept will be given to, someone with a known or possible hypersensitivity to latex.

Pregnancy:
• The effects of etanercept in pregnant women are not known, and so the use of etanercept during pregnancy is not recommended. Women using etanercept should not become pregnant. If the patient becomes pregnant, you should consult with the patient's doctor.

For Placebo: your condition will not be treated, so it may stay the same or worsen.
In addition, there may be other side effects or risks that are not known at this time.

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

- Subjects (>=18 years of age) with a clinical diagnosis of moderate-to-severe chronic plaque psoriasis (defined by >=10% body surface area [BSA] involvement, PGA score >=3, and PASI score >=12 at Baseline [Visit 2]), - Subjects must have a diagnosis of predominantly plaque psoriasis for >=6 months (as determined by subject interview and confirmation of diagnosis through physical examination by investigator), - Subjects must be considered candidates for phototherapy or systemic therapy.

Exclusion criteria

- Subject has predominantly non-plaque forms of psoriasis specifically

erythrodermic psoriasis, predominantly pustular psoriasis, medication-induced or medication-exacerbated psoriasis, or new-onset guttate psoriasis., - Subject with current, or history of, severe psoriatic arthritis and is well-controlled on current therapy., - Women of childbearing potential who are pregnant, intend to become pregnant (within 6 months of completing the trial) or are lactating., - Subject who is expected to require topical therapy, phototherapy, or systemic therapy during the trial., - Presence of any infection or history of recurrent infection requiring treatment with systemic antibiotics within 2 weeks prior to Screening, or severe infection (eg, pneumonia, cellulitis, bone or joint infections) requiring hospitalization or treatment with IV antibiotics within 8 weeks prior to Screening., - Subject with any previous use of etanercept, MK-3222 or other IL-23/Th-17 pathway inhibitors, including p40, p19, and IL-17 antagonists., - Subject is sensitive or allergic to latex., - Subject with evidence of active or untreated latent tuberculosis (TB) according to Screening criteria specified in the protocol. Prophylactic treatment for latent TB as per local guidelines must be initiated at least 4 weeks prior to first administration of study medication.

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):	18-12-2013
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Enbrel
Generic name:	Etanercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	nvt
Generic name:	MK-3222

Ethics review

Approved WMO Date:	03-04-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-07-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-10-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-06-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	22-07-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-08-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-12-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-02-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-03-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-09-2016
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-09-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-11-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-10-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-07-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	25-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-12-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-12-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-04-2020
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	EUCTR2012-001377-88-NL
CCMO	NL43512.056.13

Study results

Date completed: 19-05-2020

Results posted: 29-09-2023

Actual enrolment: 8

First publication
07-09-2023