A Phase 1/2 Randomized, Blinded, Dose-escalation Study to Evaluate the Safety and Efficacy of Intrathecal Administration of AAV9-ABCD1 Gene Therapy (SBT101) in Adult Patients with Adrenomyeloneuropathy

Published: 29-03-2022
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This study has been transitioned to CTIS with ID 2024-518451-39-00 check the CTIS register for the current data. • To characterize the safety and tolerability of one-time IT administered SBT101 in adults diagnosed with AMN.• To characterize the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON56436

Source
ToetsingOnline

Brief title
PROPEL

Condition

- Neuromuscular disorders

Synonym
Adrenoleukodistrophy; degenerative neurological disease

Research involving

Human

Sponsors and support

Primary sponsor: SwanBio Therapeutics, Ltd.
Source(s) of monetary or material Support: Pharmaceutical Company

Intervention

Keyword: Adrenomyeloneuropathy, Gene therapy

Outcome measures

Primary outcome

Percentage of patients with at least 1 Grade III or Grade IV AE that is at least possibly related to SBT101 at Month 24, as reported by the patients or observed by the Investigator, after SBT101 treatment

Secondary outcome

Changes in the 6-minute Walk Test (6MWT) at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Changes in the 2-minute Walk Test (2MWT) at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Changes in the 5 times Sit-to-Stand Test (5XSST) at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Changes in postural body sway amplitudes at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Proportions of patients with Expanded Disability Status Score (EDSS) of >=5.5 at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Proportions of patients with increased anti-spasticity medication dose at Month 12 and Month 24 compared to controls, and compared to the reference changes determined by the prospective SBTNHX-CT901 study.

• Changes in Timed Up and Go (TUG) at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in Dual-task TUG (TUG-DT) at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in the Balance Evaluation System Test (miniBESTest) at Month 12 and Month 24 compared to controls, and compared to the changes observed in the

prospective SBTNHX-CT901 study.

• Changes in the Clinical Global Impression (CGI; performed by a qualified professional) score at Month 12 and Month 24 compared to controls.

Changes in the Patient Global Impression of Severity (PGI-S), Patient Global Impression of Severity - Balance (PGI-S Balance), and Patient Global Impression of Change - Balance (PGI-C Balance) scores at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Percentage of patients with at least 1 Grade III or Grade IV AE that is at least possibly related to SBT101 at Month 60, as reported by the patients or observed by the Investigator, after SBT101 treatment.

Changes in the Severity Score System for Progressive Myelopahty (SSPROM) score at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in the Multiple Sclerosis Quality of Life-54 (MSQoL-54) score at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in the Multiple Sclerosis Walking Scale

(MSWS-12) score at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in the Urinary and Bowel Questionnaire at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in the conduction velocity, distal latency, and F-wave of peroneal compound motor action potential at Month 12 and Month 24 compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Changes in lower kinematics and kinetics parameters at Month 12 and Month 24 compared to controls, and compared to the changes observed in the SBTNHX-CT901 study.

• Changes in the daily life profile, activity bouts, and sleep parameters, as measured by the Centerpoint Watch, compared to controls, and compared to the changes observed in the prospective SBTNHX-CT901 study.

• Clinical Global Impression-Change by visit

• Changes in the following parameters at Month 12 and Month 24 compared to controls:

o Serum and/or CSF neurofilament light chain (NfL),

lysophosphatidylcholine (LPC) very long chain fatty acids

(VLCFAs), and VLCFAs.

o Brain and cervical spine MRIs (diffusion tensor imaging [DTI],

magnetization transfer [MT], and spectroscopy parameters).

Study description

Background summary

Adrenoleukodystrophy (ALD) is an inherited progressive neurodegenerative disorder caused by a mutation in the adenosine triphosphate (ATP)-binding cassette transporter subfamily D member 1 (ABCD1) gene. This gene is localized to the X chromosome and encodes a peroxisomal ATP-binding cassette half-transporter responsible for transporting very long chain fatty acids (VLCFAs) from the cytosol into the peroxisome for degradation. A mutation in the ABCD1 gene results in reduced degradation and accumulation of saturated VLCFAs in tissues and body fluids (i.e., brain, nervous system, adrenal glands), which in turn leads to demyelination, central nervous system (CNS) deterioration, and neurologic defects. The accumulation of VLCFAs - particularly C26:0 - is acknowledged to be the biochemical hallmark of ALD and serves as a diagnostic marker.

The principal phenotypes observed in males with ALD are adrenomyeloneuropathy (AMN), the cerebral demyelinating form of ALD (cerebral ALD), and adrenal insufficiency (Addison*s disease). There are marked differences in the clinical presentations of these phenotypes, including the age of onset, pathology, and progression of disease, indicating that AMN, cerebral ALD, and adrenal insufficiency are etiologically related but distinct disease states that necessitate different treatment strategies. Among these disease states, AMN is the most common.
It is characterized by a slowly progressive axonopathy affecting sensory ascending and motor descending spinal cord tracts that manifests in aging patients, with 100% penetrance in men.

In AMN, the largest and longest axons in the spinal cord sustain the greatest degree of damage and a dying back pattern of axonal degeneration has been reported in the dorsal columns (gracile fasciculus, and the cuneate fasciculus) and corticospinal tracts; the large myelinated fibers appear to be the most susceptible.

Onset typically occurs between the ages of 20 and 30 years in male patients;

the initial symptoms include poor balance and falls, progressive stiffness and weakness of the legs, impaired vibration and position senses, sphincter disturbances, sexual dysfunction, scarce scalp hair (alopecia), and impaired adrenocortical function. Patients with AMN typically start to use walking aids 13 to 16 years after onset of AMN symptoms.

Approximately half of patients with AMN show some degree of brain involvement on magnetic resonance imaging (MRI) or clinical examination. Abnormal MRI signals of white matter have been observed, but no gadolinium enhancement is present, indicating an intact blood brain barrier and the absence of an acute inflammatory process. In 20 to 60% of patients with AMN, brain involvement becomes severely progressive and leads to serious cognitive and behavioral disturbances that may progress to total disability and death. In two-thirds of patients with AMN, neurological disability progresses slowly and, within 10 to 15 years, motor disability becomes severe and patients require the use of walking aids.

Mutation in the ABCD1 gene affects adrenal glands, and primary adrenal insufficiency is common in males with AMN. Adrenal insufficiency can be treated using steroid (prednisone/prednisolone) replacement therapy. Undiagnosed or inappropriately treated adrenal insufficiency or rapid change of steroid dose can progress to adrenal crisis, which can lead to rapid deterioration and death if left untreated.

There are no curative treatments available for AMN. Current therapeutic strategies are aimed at eliminating or ameliorating symptoms that affect functional abilities and/or impair quality of life. These include, among others, monitoring of patients to prevent the development of secondary impairment or disability, such as lumbar disc degeneration and chronic immobility caused by gait disturbances; managing spasticity through physiotherapy and the use of anti-spasticity medications; and reducing urinary symptoms through physiotherapy, anticholinergic drugs, and long-term catheterization. These therapies can somewhat improve the quality of life of patients; however, without addressing the genetic root cause of AMN, patients are left with a progressive disorder that leads to lifelong disability.

Study objective

This study has been transitioned to CTIS with ID 2024-518451-39-00 check the CTIS register for the current data.

• To characterize the safety and tolerability of one-time IT administered SBT101 in adults diagnosed with AMN.
• To characterize the efficacy of IT administered SBT101 in adults diagnosed with AMN.
• To assess the change in quality of life, patient abilities, and daily living activities from Baseline to Month 12 and Month 24.

• To evaluate the safety of the catheter used to infuse SBT101 intrathecally in Europe (European only objective)

Study design

This is a Phase 1/2 randomized, blinded, dose-escalation study to evaluate the safety and efficacy of intrathecal (IT) administration of SBT101, a recombinant adeno-associated virus serotype 9 (AAV9) containing a functional copy of the human adenosine triphosphate (ATP)-binding cassette transporter subfamily D member 1 (ABCD1; hABCD1) gene, in adult patients with adrenomyeloneuropathy (AMN) aged 18-65 years. The core study consists of a parallel design with a control crossover in Part 2. During dose escalation, Dose Level 1 and Dose Level 2 patients will receive open-label SBT101 to establish safety and the maximum tolerated dose (MTD). After confirmation of safety, the MTD will be selected for the randomized, blinded Cohort 3 dose expansion phase. Patients will receive a single dose of SBT101 via IT route and will be followed for safety and efficacy for 5 years.
The study consists of two parts after infusion of SBT101:
• Part 1: A 24 month core study period to evaluate the safety and potential impact of SBT101 on disease progression. Part 1 will consist of 2 phases:
o Dose Escalation Phase (open-label): Two (2) doses of SBT101 will be evaluated to establish the maximum tolerated dose (MTD).
• Dose Level 1 Cohort - 1.0E14 vector genomes (vg)
• Dose Level 2 Cohort - 3.0E14 vg
o Dose Expansion Phase (randomized, blinded): Additional patients will be enrolled to receive SBT101 at the MTD
• Part 2: An unblinded 3-year long-term safety follow-up period with annual follow-up visits to evaluate the safety of SBT101 and disease progression.
Informed consent will be obtained from all patients at the Screening Visit (Visit 1) prior to conducting any screening procedures to assess study eligibility. The duration of the study for patients receiving SBT101 will be up to 66 months, including up to 4 months for Screening, the 24-month core study period (i.e., Part 1), and 36 (±2) months for long-term safety follow-up (i.e., Part 2). The duration of the study for patients randomized to the control arm who choose to receive SBT101 after the cohort primary analysis will be a maximum of 90 months, including up to 4 months for Screening, the 24-month core study period, another 24 months for follow-up post-administration of open-label SBT101, and 36 (±2) months for long-term safety follow-up.
In Part 1, a minimum of 16 patients will be enrolled in 2 phases: Dose Escalation Phase and Dose Expansion Phase. The Dose Escalation Phase aims to establish the MTD. In the Dose Escalation Phase, a minimum of 8 patients will be enrolled, with a minimum of 4 patients enrolled to Dose Level (1.0E14 vg) and a minimum of 4 patients enrolled to Dose Level 2 (3.0E14 vg). In the Dose Expansion Phase, an additional 8 patients will be randomized to treatment on a 3:1 basis to receive SBT101 at MTD. The decision on dose escalation and treatment of additional patients at each dose level during the Dose Escalation Phase will be made after review of safety by the independent Data Safety

Monitoring Board (DSMB) and the Sponsor.
• An independent DSMB will be established; members will include at least 3 independent physicians with expertise in neurological diseases or gene therapy, and an independent statistician.
• The Sponsor*s Medical Monitor will review the safety data after each patient completes the Day 30 Visit before treatment of subsequent patients within that Dose Level Cohort.
• The DSMB will review the available safety data after at least 2 patients complete the Day 30 visit at each Dose Level prior to recommending treatment of additional patients or initiation of dose escalation or expansion.
The Sponsor, in consultation with the DSMB, may:
• Decide to investigate an additional dose of SBT101 in the Dose Expansion Cohort different than Dose Level 1 and Dose Level 2;
• Elect to increase or decrease the number of patients in a Dose Level Cohort during the study.
All patients in the control arm will have the option to be treated with open-label SBT101 after the last patient in the cohort has completed the Month 24 Visit. Patients who opt to be treated with open-label SBT101 must continue to meet all exclusion and inclusion criteria (except for inclusion criterion (#1 and #3) and exclusion criterion (#3)). If they choose to be treated with open-label SBT101, they will restart all procedures at Day 1 and will be followed for another 5 years.

Intervention

The study consists of two parts after infusion of SBT101:

• Part 1: A 24 month core study period to evaluate the safety and potential impact of SBT101 on disease progression. Part 1 will consist of 2 phases:
Phase 1: se Escalation Phase (open-label): Two (2) doses of SBT101 will be evaluated to establish the maximum tolerated dose (MTD).
• Dose Level 1 Cohort - 1.0E14 vector genomes (vg)
• Dose Level 2 Cohort - 3.0E14 vg

Phase 2: Dose Expansion Phase (randomized, blinded): Additional patients will be enrolled to receive SBT101 at the MTD

• Part 2: An unblinded 3-year long-term safety follow-up period with annual follow-up visits to evaluate the safety of SBT101 and disease progression.

Study burden and risks

Potential risks with the SBT101 administration:

Elevated Transaminases

Elevation in liver enzymes is the most common side effect associated with this type of gene therapy. This can be controlled by taking steroids. The patient will be given these medications before and after the procedure, and the levels of these liver enzymes will be closely monitored for at least 3 months after procedure with SBT101.

Low Platelet Counts
This type of gene therapy, when given through an IV, has been shown to cause decreased platelet counts. The risk of this event may be lower in this study because The IMP is administered via Intrathecal infusion.

Cardiac Adverse Events
Elevation in cardiac enzyme, troponin, indicating a problem with the heart has been reported with IV administration of AAV9 gene therapy. The risk of this event may be lower in this study because the study drug is not administered intraveneously.

Spine and Dorsal Root Ganglion Adverse Events
Adverse inflammatory responses in the spinal cord and/or structures (ganglions) transmitting sensory nerves have been reported with IT AAV administration in animal studies (Hordeaux et al., 2020; FDA, 2021). Etiology of the pathology is unknown. Systemic corticosteroids and immunosuppressive will be administered before and after the procedure and for at least 3 months, to prevent the inflammatory response. Assessment of sensation and nerves carrying the sensory information will be monitored for at least 3 months after procedure.

Shedding viral particles
Since SBT101 is a virus, treated patients may be able to shed the virus from their body, for example in their bodily fluids. This type of virus is non-replicating, meaning it cannot make more of itself, so that the risk of the virus infecting other people is extremely low. Reliable barrier contraception for 6 months post dose is mandatory.

Creation of new medical conditions
Viruses can insert their own DNA into the DNA of the animal they infect. If this happens, there is a risk that new medical conditions could occur in the animal, such as developing tumors, because the animal*s DNA has been changed. The risk of this happening with the type of virus being used in this study is considered low. This virus does not typically inert its DNA into the animal*s DNA and there are no reports of this occurring in any of the previous clinical trials which have used this type of virus.

Risks Related to methylprednisolone/prednisolone Use
Common side effects that can occur with short-term use include the following:
• Increased appetite
• Weight gain
• High blood pressure

• Elevated blood sugar
• Fluid retention (facial or limb swelling)
• Mood changes and depression
• Hyperactivity
• Difficulty sleeping
• Increased risk of infection

Common side effects that can occur with long-term use include the following:
• Peptic ulcer (a sore in the lining of your stomach)
• Gastrointestinal (GI) bleeding (black stools)
• Vision problem
• Suppressed adrenal gland hormone production.
• Loss of calcium from bones, which can lead to osteoporosis.
• Skin thinning and bruises.

Risk of Medical Evaluations

Blood Draws
Possible side effects of blood draws are tenderness, pain, bruising, bleeding and/or infection where the needle goes into the skin, vein, and blood. Having blood drawn may also cause nausea and light-headednes. Very rarely, the needle may damage a nerve.

Electrocardiogram (ECG):
An ECG is a recording of the electrical activity the heart and is taken by placing electrodes on the skin of chest, arms and legs. Sometimes there may be some minor skin redness or itchiness from the tabs.

MRI:
There are no known risks of receiving an MRI.

Electrophysiology (EP):
Electrodiagnostic Testing is safe and electric stimulation is too weak and short to cause an injury or permanent damage, but it can be an unpleasant feeling.

Lumbar Puncture:
A lumbar puncture is a procedure where a needle is inserted into the spinal canal between the lumbar bones in the spine. The skin will be treated with lidocaine. this can sting and burn.
Sometimes pain occurs if a nerve is hit during the procedure. The pain is usually sharp and quick and doesn*t persist.
There is a slight risk of infection because the needle breaks the skin's surface.
There is an additional risk of infection from use of a catheter to infuse the study drug.
It is also possible to have short-term numbness of the legs, or lower back pain

may be experienced.
More common is a severe headache which should resolve within a few days. The risk of headache and the need for a blood patch may be increased as compared to a standard lumbar puncture. The needle size and length of the infusion may increase the risk of needing a blood patch.

Potential benefits

The study drug may improve gait and balance affected by AMN as well as improve overall health and well-being, but there is no guarantee of any benefit. The information from this study might help to develop better treatments in the future for people with AMN or other similar diseases, considering teh there no available therapies at present.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Male adults aged >=18 and <= 65 years
2. Diagnosed with X-linked adrenoleukodystrophy (ALD)), including proven mutation in the ABCD1 gene through confirmatory genetic testing, and supported by historically elevated VLCFA.
3. Clinical evidence of spinal cord involvement with EDSS score between 1 and 4.5 and pyramidal function score of >=1 in the Functional System Score of the EDSS. Signs of pyramidal tract dysfunction don't include hyperreflexia.
4. Must agree to use reliable double-barrier contraception methods (e.g.,
condom and 1 other form of contraception for female sexual partners that are of childbearing potential, such as diaphragm, intrauterine device, spermicidal jelly, and/or hormonal contraceptive) and to not donate sperm for at least 6 months following the IMP procedure.
5. For patients who are receiving any other treatment for ALD, including off-label medications and/or supplements (e.g., antioxidants, Lorenzo's oil, statins, etc.) or physical rehabilitation support, such treatments must have been at a stable dose and/or frequency for >=4 weeks prior to Screening and patients must agree to continue at the same dose and/or frequency through Part 1 of the study.
6. The patient provided written informed consent prior to any study procedures being performed

Exclusion criteria

1. Presence of inflammatory cerebral disease, established by radiographic review of brain MRI demonstrating a Loes score >=0.5 on the 34-point scale, except for the abnormalities that can be observed in patients with AMN without inflammatory cerebral demyelination with Loes score <=4.
2. Pathological changes identified on brain MRI including all lesions from previous diagnosis of inflammatory cerebral disease with Loes score >=0.5 on the 34-point scale, except for the abnormalities that can be observed in patients with AMN without inflammatory cerebral demyelination with Loes score <=4
3. 15 years or more have elapsed since the initial onset of myeloneuropathy manifestations, such as walking or running difficulties, bladder dysfunction, increased muscular tone, spasticity, weakness, balance problems, etc.
4. Contraindications for MRI procedure and/or contrast materials.
5. History of a brain or spinal cord disease that would interfere with lumbar puncture procedures, CSF circulation, and/or safety

assessments.
6. Contraindication to steroids, sirolimus, tacrolimus, and/or anesthetic medications.
7. Contraindication to SBT101 and/or any of its ingredients.
8. Unstable adrenal function (e.g., untreated or inappropriately treated adrenal insufficiency).
a. Adrenal function will be evaluated through laboratory assessments of serum cortisol, plasma adrenocorticotropic hormone (ACTH), plasma renin, aldosterone, sodium, and potassium levels at Screening. Monitoring of replacement therapy will be mainly clinical. Determination of inappropriately treated adrenal insufficiency will be made by the Investigator in consultation with the Medical Monitor.
b. Patients who meet the following criteria will be considered to have adrenal insufficiency: (i) basal cortisol concentration <275 nmol (10 µg/dL) in the morning (i.e., 6 AM to 10 AM) and (ii) plasma ACTH >= 2 × upper limit of normal (ULN).
9. Positive for human immunodeficiency virus (HIV) type 1 or 2 (HIV-1, HIV-2), hepatitis B virus (HBV), or hepatitis C virus (HCV).
a. Patients who have been vaccinated against HBV (e.g., HBV surface antibody-positive) who are negative for other markers of prior HBV infection (e.g., HBV core antibody-negative) are eligible.
b. Patients who are positive for anti-HCV antibodies are eligible, as long as they have a negative HCV load as measured by quantitative polymerase chain reaction (qPCR).
10. Presence of a clinically significant active bacterial, viral, fungal, parasitic, or prion-associated infection.
11. History of diabetes or abnormal fasting plasma glucose (>=126 mg/dL) or hemoglobin A1C >=6.5%.
12. Patients who have received a gene therapy.
13. Current use of medications that could potentially lead to changes in intracranial pressure (e.g., levothyroxine, vitamin A supplementation, oral contraceptives, tetracycline, acetazolamide [Diamox]).
14. Patients who are currently using strong CYP3A4 inducers or strong CYP3A4 inhibitors, and are unwilling or unable to stop prior to and during the immunosuppression regimen.
15. Patients who are currently receiving or have received an investigational drug or procedure within 3 months prior to Screening. The use of investigational drugs is prohibited throughout Part 1 of the study.
16. Patients with unstable, clinically significant neurologic (other than AMN), psychiatric, cardiovascular, ophthalmologic, pulmonary, hepatic, renal, metabolic, gastrointestinal, urologic, immunologic, hematopoietic, and/or endocrine disease (other than adrenal insufficiency) and/or other abnormality that may impact the ability to participate in the study or that may potentially confound the study results. It is the responsibility of the Investigator to assess clinical significance; however, consultation with the Sponsor's Medical Monitor may be

warranted.
17. Patients who, in the opinion of the Investigator, have any other medical or psychological condition or social circumstances that would impair their ability to participate reliably in the assessments, or who may increase the risk to themselves or others by participating.
18. Patients who are an immediate family member, study site employee, or are in a dependent relationship with a study team member involved in the conduct of this study (e.g., spouse, parent, child, sibling).

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2023
Enrollment:	5
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Generic name:	Genetic modified organism

Ethics review

Approved WMO

Date:	29-03-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	14-12-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-02-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-08-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-09-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-10-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-01-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-02-2024

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-04-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-04-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-05-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-06-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EU-CTR	CTIS2024-518451-39-00
EudraCT	EUCTR2021-004410-19-NL
CCMO	NL81033.000.22