A phase 1/2a, open-label trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple ascending doses of intrathecally administered VO659 in participants with spinocerebellar ataxia types 1, 3 and Huntington*s disease

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This study has been transitioned to CTIS with ID 2024-514328-18-00 check the CTIS register for the current data. Primary Objective:To evaluate the safety and tolerability of multiple doses of intrathecal lumbar bolus administrations of VO659 in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53759

Source
ToetsingOnline

Brief title
VO659-CT01

Condition

- Other condition
- Neurological disorders congenital

Synonym
Huntington's Disease, Spinocerebellar ataxia

Health condition

a group of rare, inherited, genetic disorders that affect specific parts of the brain, including the cerebellum (the center of motor coordination), brain stem and spinal cord. These disorders can cause problems such as problems with balance, coordination, walking, swallowing and speaking.

Research involving
Human

Sponsors and support

Primary sponsor: VICO Therapeutics B.V.
Source(s) of monetary or material Support: VICO Therapeutics B.V.

Intervention

Keyword: Huntington's disease, Spinocerebellar ataxia type 1, type 3

Outcome measures

Primary outcome

Primary Objective:

To evaluate the safety and tolerability of multiple doses of intrathecal lumbar

bolus administrations of VO659 in participants with clinically manifest SCA1,

SCA3, or HD

Endpoints:

• Incidence and dose relationships of treatment-related:

o Adverse events (AEs),

o Serious adverse events (SAEs),

o Adverse events of special interest (AESI),

o Severe events (NCI-CTCAE Grade 3 or higher).

• Changes in clinical safety parameters including physical and neurological examinations, vital signs, body weight, ECG ,cardiac monitoring, suicidal ideation and behavior risk monitoring by the Columbia Suicide Severity Rating Scale (C-SSRS), and review of structural MRI scans

• Changes in laboratory safety parameters in blood (haematology, haemostasis, clinical chemistry), CSF (cell counts, protein, glucose), and urin (urinalysis).

• Adverse changes in clinical status based on exploratory clinical, biochemical and neuroimaging assessments

Secondary outcome

Secondary Objective : To characterize the CSF and blood PK profile of single and multiple doses of intrathecal lumbar bolus administrations of VO659 in participants with clinically manifest SCA1, SCA3 or HD Endpoints: • The CSF concentration-time profile of VO659, including the derived PK parameter of elimination half-life (t1/2), if possible. • The plasma concentration-time profile of VO659, including the derived PK parameters such as the area under the curve (AUC), peak plasma concentration (Cmax), elimination half-life (t1/2) Exploratory Objectives: • To assess the pharmacodynamic (PD) profile of single and multiple doses of intrathecal lumbar bolus administrations of VO659, including target engagement and off-target effects based on biochemical biomarkers and MRI neruoimaging assessments in participants with clinically manifest SCA1, SCA3 or HD. • To assess effects on clinical outcome assessments of intrathecal lumbar bolus administrations of VO659 in participants with clinically manifest SCA1, SCA3 or HD. Endpoints: • Changes in mutant ATXN1 (in participants with SCA1) mutant ATXN3 (in participants with SCA3) or mutant HTT (in participants with HD) in CSF and blood.* • Changes in total ATXN1, total ATXN3, total HTT in CSF and blood.* • Changes in biomarkers indicative of neurodegeneration, such as NfL, total tau, GFAP, and UCH-L1 in CSF and the blood • Changes in biomarkers indicative of inflammation, such as C3a, IL-1β, IL-6, TNFα and YKL-40 (CH3-L1) in CSF and the blood • Changes in neuroimaging outcomes, such as the volume of whole brain and brain regions of interest (including but not limited to the cerebellum, pons, brainstem, and striatum), diffusion MRI, quantitative MRI for iron content (R2* mapping), MRS (optional, only at select trial sites), and OCT (only at select trial sites) • Changes in clinical outcome measures, such as SARA, 9-HPT, FARS (part I & II), INAS (participants with SCA1 or SCA3); UHDRS TFC, FAS, IS, TMS/DCL (participants with HD), MoCA, SDMT, CGI-S, and CGI-C (all participants). • Changes in Patient-reported outcomes, such as PGI-S and PGI-C ECG QTcF-blood PK relationship analysis and other interval analyses. *When an assay for a given target gene is not available by the end of

the trial, the analysis will not be performed.

Study description

Background summary

Spinocerebellar ataxia types 1 and 3 (SCA1 and SCA3), as well as Huntington*s disease (HD) are severely debilitating disorders that are currently incurable. Preclinical data suggest that VO659 may be a disease-modifying therapy in these disorders through its binding to the expansion of cytosine, adenine, and guanine trinucleotide repeats (CAG repeats) in the ribonucleic acid (RNA) transcripts of the causative genes, thus interfering with RNA translation and reducing the intracellular level of the harmful mutant proteins. The present trial is the first-in-human (FiH) evaluation of VO659 with the primary focus on the assessment of safety and tolerability of dose levels that will potentially be used in further development of VO659. These assessments will be done in a relevant population of SCA1, SCA3 and HD participants, representative of the entire group of polyQ diseases. Toxicological data available to date suggest that the VO659 treatment regimen to be evaluated under the current protocol should not pose an undue risk to the trial participants, particularly considering the initial low dose levels and monitored, gradual dose-escalation. Trial-required procedures are all routine in the neurological practice and entail minimal risks that are mostly manageable.

Study objective

This study has been transitioned to CTIS with ID 2024-514328-18-00 check the CTIS register for the current data.

Primary Objective:

To evaluate the safety and tolerability of multiple doses of intrathecal lumbar bolus administrations of VO659 in participants with clinically manifest SCA1, SCA3, or HD

Secondary Objective:

To characterize the CSF and blood PK profile of single and multiple doses of intrathecal lumbar bolus administrations of VO659 in participants with clinically manifest SCA1, SCA3 or HD

Exploratory Objectives:

• To assess the pharmacodynamic (PD) profile of single and multiple doses of intrathecal lumbar bolus administrations of VO659, including target engagement and off-target effects based on biochemical biomarkers and MRI neruoimaging assessments in participants with clinically manifest SCA1, SCA3 or HD.
• To assess effects on clinical outcome assessments of intrathecal lumbar bolus administrations of VO659 in participants with clinically manifest SCA1, SCA3 or HD.

Study design

This study is designed as a phase 1/2a, open-label, multiple ascending dose, multi-center trial.

Dose escalation is planned in up to five dose levels. A schematic overview of the trial design is presented in Figure 1 of the protocol.
A summary of the planned dose levels and distribution of participants per indications is presented below in Table 5 of the protocol.
For considerations regarding sample size determination, see Section 9.6 of the protocol.

Intervention

VO659 is a 2*-O-methyl-modified 21-mer antisense oligonucleotide with a phosphorothioate backbone targeting CAG repeats in mRNA transcripts, provided as a stock solution for dilution and IT administration on Days 1, 29, 57 and 85.

Study burden and risks

General Risks:

There is the risk that your disease symptoms will not get better or may even get worse during the trial.

Risks of the study drug VO659:

There is the risk that you could have side effects from the study drug. This is the first time this study drug is given to humans. Studies in animals showed the following side effects:

• Absence of reflexes in the legs
• Lack of muscle coordination affecting walking (reduced ability or inability to control legs)
• Involuntary muscle shaking (muscle tremor). These effects were more severe at the highest doses tested in monkeys. This happened at doses of the study drug that are higher than what will be used in this clinical trial. The lower doses

tested were safe and well-tolerated in animals.
• Changes in heart rate, blood pressure and the heart*s electrical activity.
These effects were only observed at the highest doses tested in animals.

These side effects are expected for this type of drug, but these might be different in humans.

In studies with similar drug types (antisense oligonucleotides) which have been administered in a similar way as the study drug VO659, most side effects were related to the injection in the lower spine, such as infection or inflammation of the lining of the brain and spinal canal, bleeding, or a build-up of fluid in the brain called hydrocephalus. Sometimes people have had headaches, falls, back pain, pain in leg, dizziness, or neck pain.
It is known that this type of study drug in high doses can cause the following side effects: toxic effects on the kidney, toxic effects on the liver, stimulation of the immune system.
In a clinical trial with another study drug with a similar way of working, some side effects were seen at high dose levels. There was an increase in the volume of CSF in certain spaces of the brain areas called ventricles (which are filled with CSF). Rarely, persons with this volume increase needed the excess fluid to be drained surgically. There was an increase in the count of immune cells and an increase in a marker for the loss of brain structure and function was observed. Although VO659 is aimed to work against faulty SCA1, SCA3 and HD genes, there is a possibility that it may affect other genes that have *CAG repeats* as well. What the consequences of that might be is currently unknown.

You should immediately contact the investigator if you experience any of the side effects listed above or if you notice or feel anything different, regardless of whether or not you think it has to do with the trial. You will be monitored closely after you have received the injection with the study drug for any side effects or changes in your health.

When you experience side effects, it is possible that you have to stop the trial treatment temporarily or completely in order to resolve the side effects. The investigator might give you other drugs to reduce the side effects.

Risks and discomforts of the examinations:

The examinations of the trial may cause the following discomforts and risks:

Blood collection:
The total volume of blood that will be collected from you throughout the trial is approximately 600 ml (over 10 months). This is approximately the same blood volume that is collected during a single blood donation. Taking blood samples may cause pain, bleeding, bruising or infection around the injection site. Some participants may feel dizzy or even faint during or after the procedure. There

is a small risk of nerve damage with permanent pain. The staff who take the blood will do all that they can to minimize these discomforts.

Injection into, and cerebrospinal fluid (CSF) collection from, the space around your spinal cord:
The injection into your lower spinal cord (intrathecal injection) and CSF sampling may result in lower back pain during and after the procedure and/or headache. Spinal cord or nerve injury, CSF leaks, bleeding, systemic and local infections may occur.

ECG:(heart tracing) and continuous cardiac monitoring:
When an ECG is taken, it is possible that your skin reacts to the electrodes (a set of sticky patches) which are placed on your chest. This irritation usually disappears soon after the electrodes have been removed. For the continuous cardiac monitoring these electrodes need to stay on for 12 hours, which may become uncomfortable and itchy. You are not restricted in your movements during these 12 hours.

Brain scan (MRI, MRS):
An MRI/MRS machine is magnetic. It is therefore not possible to undergo an MRI/MRS scan when you have an implanted electronic device (for example a pacemaker, cochlear implant (CI), etc.) or certain implanted metal or magnetic devices. Tell the doctor about any implants you have.

It is possible to feel claustrophobic (feeling scared of a small space) in an MRI machine, as you will have to lie still in a narrow space for approximately 20-30 minutes. MRI scans often include banging and other loud sounds.

Optical Coherence Tomography (OCT)
There aren't any risks or side effects associated with OCT scans, except possibly some discomfort, dryness or eye fatigue.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusive Criteria: Participants are eligible to be included in the trial only if all of the following criteria are met: Informed Consent 1. Provide written informed consent (signed and dated). Patients should be assessed for their ability to give informed consent using the Evaluation to Sign Consent tool. Age 2. Is >=25 and <=60 years of age inclusive, of any gender, at the time of signing the informed consent. Type of Indications and Disease Characteristics 3. Have SCA1, SCA3 or HD meeting one of the following criteria: a. SCA1 or SCA3: mild to moderate disease with a Scale for Assessment and Rating of Ataxia (SARA) score of >=3 and <=18, b. HD: early manifested, Stage I disease with a Total Functional Capacity (TFC) Score of >=11 and <=13 and a Unified Huntington*s Disease Rating Scale (UHDRS) Diagnostic Confidence Level (DCL) of 4. 4. Have genetically confirmed disease, defined by increased cytosine, adenine, and guanine (CAG)-repeat length in the disease-causing allele by direct DNA testing (detail see Section 8.6.1), for each indication the requirements are: a. SCA1: >=41 contiguous, uninterrupted CAG repeats in ATXN1 b. SCA3: >=61 repeats in ATXN3 c. HD: >=36 CAG repeats in HTT. NOTE: Genetic testing will be performed during screening, which will serve as a reference for criterion. 5. Have good general health apart from having SCA1, SCA3, or HD at the discretion of the investigator. NOTE: In the presence a chronic illness (e.g., hypertension), a stable, well-controlled disease in the opinion of the investigator that will not impact the primary objectives of the trial is allowed. Weight 6. Have body weight of >= 50 kg and body mass index (BMI) within the range of 18-32 kg/m2 (inclusive). Reproductive status and Contraceptive/Barrier Requirements 7. Is willing to follow contraceptive requirements per local regulations regarding the methods of contraception for those participating in clinical trials. In case local regulations deviate from the contraception methods listed in Section *10.4, local regulations apply and will be described in the Informed Consent Form (CF). a. Male participants: Applicable for Europe (NOTE: details according to the Clinical Trial Facilitation Group (CTFG) Contraception Guidance Version 1.1, issued 2020; see Section 10.4): Non-sterilized males who are sexually active with a female partner of

childbearing potential: Agreement to use a condom as a method of contraception during the entire period from first IMP (VO659) administration up to 90 days after the last IMP administration and not to donate sperm during this period. Additionally, contraception for the female partner of childbearing potential should be considered. b. Female participants: Applicable for Europe (NOTE: Details according to CTFG Contraception Guidance version 1.1, issued 2020; see Section 10.4): Women of childbearing potential: a negative result in a pregnancy test at screening and prior to each IMP administration AND agreement to practice a highly effective method of contraception during the entire period from informed consent up to 6 months after the last IMP administration. A woman is considered of childbearing potential, i.e., fertile, following menarche and until becoming postmenopausal unless permanently sterile. Permanent sterilization methods include hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. A postmenopausal state is defined as no menses for at least 12 months without an alternative medical cause. Women under the age of 55 years must have both no menses for at least 12 months and a follicle-stimulating hormone (FSH) level >40m IU/mL (while not on any therapy that may interfere with FSH levels) in order to confirm menopause. In the absence of 12 months of amenorrhea, an FSH measurement in itself is insufficient to establish menopause. Key inclusion criteria: Participants are eligible to be included in the trial only if all of the following criteria are met: Informed Consent 1. Provide written informed consent (signed and dated). Patients should be assessed for their ability to give informed consent using the Evaluation to Sign Consent tool. Age 2. Is >=25 and <=60 years of age inclusive, of any gender, at the time of signing the informed consent. Type of Indications and Disease Characteristics 3. Have SCA1, SCA3 or HD meeting one of the following criteria: a. SCA1 or SCA3: mild to moderate disease with a Scale for Assessment and Rating of Ataxia (SARA) score of >=3 and <=18, b. HD: early manifested, Stage I disease with a Total Functional Capacity (TFC) Score of >=11 and <=13 and a Unified Huntington*s Disease Rating Scale (UHDRS) Diagnostic Confidence Level (DCL) of 4. 4. Have genetically confirmed disease, defined by increased cytosine, adenine, and guanine (CAG)-repeat length in the disease-causing allele by direct DNA testing (detail see Section 8.6.1), for each indication the requirements are: a. SCA1: >=41 contiguous, uninterrupted CAG repeats in ATXN1 b. SCA3: >=61 repeats in ATXN3 c. HD: >=36 CAG repeats in HTT. NOTE: Genetic testing will be performed during screening, which will serve as a reference for criterion. 5. Have good general health apart from having SCA1, SCA3, or HD at the discretion of the investigator. NOTE: In the presence a chronic illness (e.g., hypertension), a stable, well-controlled disease in the opinion of the investigator that will not impact the primary objectives of the trial is allowed. Weight 6. Have body weight of >= 50 kg and body mass index (BMI) within the range of 18-32 kg/m2 (inclusive). Reproductive status and Contraceptive/Barrier Requirements 7. Is willing to follow contraceptive requirements per local regulations regarding the methods of contraception for those participating in clinical trials. In case local regulations deviate from the contraception methods listed in Section *10.4, local regulations apply and will be described in the Informed Consent Form (CF). a. Male participants: Applicable for Europe (NOTE: details according to the Clinical Trial Facilitation Group (CTFG) Contraception Guidance Version 1.1, issued 2020; see Section 10.4): Non-sterilized males who are sexually active with a female partner of childbearing potential: Agreement to use a condom as a method of contraception during the entire period from first IMP (VO659) administration up to 90 days after the last IMP administration and not to donate sperm during this period. Additionally, contraception for the female partner of childbearing potential should be considered. b. Female participants: Applicable for Europe

(NOTE: Details according to CTFG Contraception Guidance version 1.1, issued 2020; see Section 10.4): Women of childbearing potential: a negative result in a pregnancy test at screening and prior to each IMP administration AND agreement to practice a highly effective method of contraception during the entire period from informed consent up to 6 months after the last IMP administration. A woman is considered of childbearing potential, i.e., fertile, following menarche and until becoming postmenopausal unless permanently sterile. Permanent sterilization methods include hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. A postmenopausal state is defined as no menses for at least 12 months without an alternative medical cause. Women under the age of 55 years must have both no menses for at least 12 months and a follicle-stimulating hormone (FSH) level >40m IU/mL (while not on any therapy that may interfere with FSH levels) in order to confirm menopause. In the absence of 12 months of amenorrhea, an FSH measurement in itself is insufficient to establish menopause.

Exclusion criteria

Exclusion Criteria: Participants are excluded from the trial if any of the following criteria apply: Medical Conditions 1. Have any condition that would prevent participation in trial assessments. 2. Have acute infection or febrile illness at the time of each dosing, or ongoing systemic antiviral or antimicrobial therapy that will not be completed at least three days prior to dosing. 3. Have one or more pathogenic mutation(s) in another polyQ disease gene, i.e., ATXN2, CACNA1A, ATXN7, TBP, AR, and ATN1, plus either ATXN3 and HTT (for patients with SCA1), ATXN1 and HTT (for participants with SCA3), or ATXN1 and ATXN3 (for participants with HD), in addition to the disease-causing mutation in the ATXN1 (patients with SCA1), ATXN3 (patients with SCA3) or HTT (patients with HD) gene.Pathogenic mutations are defined as: >=41 contiguous, uninterrupted CAG repeats in ATXN1; >=61 repeats in ATXN3; >=36 CAG repeats in HTT; >=38 CAG repeats in AR; >=48 CAG repeats in ATN1; >=33 CAG repeats in ATXN2; >=34 CAG repeats in ATXN 7; >=20 CAG repeats in CACNA1A; >=41 CAG repeats in TBP. 4. Have clinical diagnosis of moderate or severe chronic migraines or history of the post-lumbar-puncture headache of moderate or severe intensity requiring hospitalization or blood patch. 5. Have a brain, spinal or systemic disorder that would interfere with the LP process, CSF circulation, or safety assessments. 6. Have history of bleeding diathesis or coagulopathy, platelet count less than the lower limit of normal unless stable and assessed by the Investigator and the Medical Monitor to be not clinically significant. 7. Have a history of any malignancy or obligatory precancerous condition of any organ system, except cervical carcinoma of Stage 1B or less, or non-invasive basal cell or squamous cell skin carcinoma that has been successfully treated. 8. Have inherited or acquired immunodeficiency, including human immunodeficiency virus (HIV) infection. 9. Have positive serology for hepatitis B surface antigen (HbsAg) or active hepatitis C infection. 10. Have any known history of hypersensitivity or allergies to the antisense oligonucleotide (AON) (VO659) or any excipient contained in the IMP. 11. Have any significant (moderate or severe) acute or chronic liver or kidney disease. 12. Have deviations of any of the following laboratory parameters at screening: • Aspartate aminotransferase (AST) >2.0 x Upper Limit of normal range (ULN) • Alanine aminotransferase (ALT) >2.0 x ULN • Total bilirubin >1.5 x ULN • Platelets <100,000/µl (i.e., <100 x 109/L) • Estimated GFR (eGFR) <45 mL/min/1.73m2

based on the modification of diet in renal disease (MDRD) formula (see Section 10.5) 13. Have uncompensated cardiovascular disorder, any past or present cardiac arrhythmia, QTcF values on screening ECG of >450 ms for males and >470 ms for females, familial history of long QT syndrome or sudden unexpected death. 14. Have a history of uncontrolled hypokalemia or hypomagnesaemia. 15. Have a history of hospitalization for any major medical or surgical procedure involving general anesthesia within 6 weeks of screening or planned during the trial. 16. Have clinical evidence of acute COVID-19 or confirmed presence of COVID-19 / SARS-CoV-2 infection at any time during the screening period, or have long-term neurological consequences of Covid-19 / SARS-CoV-2 infection that have not resolved or stabilized at the time of screening. 17. Have a history of attempted suicide, suicidal ideation with a plan that required hospital admission and/or change in level of care within 12 months prior to screening. For patients with (i) a suicide ideation score >= 4 on the Columbia Suicide Severity Rating Scale (C-SSRS) within the last 12 months, (ii) a score of 3 or 4 on question 2 of the Problems Behavior Assessment for Huntington*s Disease - short form or (iii) suicidal behaviours within the last 12 months (as measured by the answer *Yes* on any of the C-SSRS Suicidal Behavior Items), a risk assessment should be done by an appropriately-qualified mental health professional (e.g., a Psychiatrist or licensed Clinical Psychologist) to assess whether it is safe for the patient to participate in the study. 18. Have a history of psychosis, bipolar disorder or schizophrenia and patients deemed to be at significant risk of an acute depressive episode, confusional state or violent behaviour. 19. Have medical, psychiatric, or other conditions that, in the judgement of the investigator, may compromise the patient*s ability to understand the patient information sheet, to give informed consent, to comply with all trial requirements, or to complete the trial. Prior/Concomitant Therapy 20. Presence of an implanted shunt for the drainage of CSF or an implanted central nervous system (CNS) catheter. 21. Treatment with another IMP, biological agent, or device within three months prior to screening, or five half-lives of the investigational agent, whichever is longer. 22. Riluzole use unless stable dose for at least four weeks prior to screening and with a dose regimen that is not anticipated to change during the trial. 23. Treatment for spasticity unless stable dose for at least four weeks prior to screening and with a dose regimen that is not anticipated to change during the trial. 24. Antidepressant or benzodiazepine use unless stable dose for at least 12 weeks prior to screening and with a dose regimen that is not anticipated to change during the trial. 25. Current or recent (within the last six months) use of antipsychotics (prescribed for psychosis) acetylcholinesterase inhibitors, memantine or amantadine. Use of antipsychotics (prescribed for treatment of motor symptoms) and/or tetrabenazine/deutetrabenazine and valproic acid is not permitted unless stable for at least 12 weeks prior to screening and with a dose regimen that is not anticipated to change during the trial. 26. Drugs known to prolong the QT interval (see Section *10.8), unless the treatment stopped at least five times the respective drug*s elimination half-life in advance of the first dosing with VO659. 27. Supplement use (e.g., coenzyme Q10, vitamins, creatine) unless stable dose for six weeks prior to screening and with a dose regimen that is not anticipated to change during the trial. 28. Antiplatelet or anticoagulant therapy within the 14 days prior to screening or anticipated use during the trial, including but not limited to dipyridamole, warfarin, dabigatran, rivaroxaban, apixaban, and edoxaban; aspirin <=100 mg/day or clopidogrel are permitted. 29. Prior treatment with an antisense oligonucleotide (including siRNA). 30. History of gene therapy or cell transplantation or any experimental brain surgery. 31. Adenoviral vector-based vaccination within 45 days of the first dosing. 32. History of chemical meningitis. Prior/Concurrent Clinical Trial Experience 33. Concurrent or

planned concurrent participation in any other clinical trial evaluating investigational medicinal products; for observational and non-interventional trials, the same applies, unless approved by the Sponsor*s Medical Expert or Medical Monitor.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-11-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-04-2023
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-07-2023
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:	22-12-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-01-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-03-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	31-05-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-09-2024
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	CTIS2024-514328-18-00
EudraCT	EUCTR2022-001314-19-NL
CCMO	NL81580.000.22