A Phase 1-3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Intrathecally Administered ION363 in Amyotrophic Lateral Sclerosis patients with Fused in Sarcoma mutations (FUS-ALS)

Published: 20-05-2022
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This study has been transitioned to CTIS with ID 2024-512163-31-00 check the CTIS register for the current data. Primary objective: To evaluate the clinical efficacy of ION363 in clinical functioning and survival in FUS-ALS patients. Secondary…

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

Summary

ID

NL-OMON54223

Source
ToetsingOnline

Brief title
ION363-CS1

Condition

- Neurological disorders congenital
- Neuromuscular disorders

Synonym
Amyotrophic lateral sclerosis (ALS); neurological disorder

Research involving
Human

Sponsors and support

Primary sponsor: Ionis Pharmaceuticals, Inc.
Source(s) of monetary or material Support: Ionis Pharmaceuticals;Inc.

Intervention

Keyword: Amyotrophic Lateral Sclerosis, Fused in sarcoma mutation, ION363

Outcome measures

Primary outcome

The primary endpoint is to evaluate the effects of ION363 vs. placebo on change from Baseline to Study Day 505 in Part 1 Cohorts A and B on functional impairment, measured by joint rank analysis of the combined assessment of the following:

• In-clinic ALSFRS-R total score

• Time of rescue. (Rescue takes place if there is a deterioration to an ALSFRS-R total score of < 15 points AND a decrease of >= 10 points from Baseline at Study Day 253, or later, that is confirmed after an interval of at least 4 weeks. Rescue means the patient may discontinue Part 1 and enter Part 2 of the study.)

• Ventilation assistance-free survival (VAFS), defined as the time to the earliest occurrence of one of the following events:

o Death

o Permanent ventilation (> 22 hours of mechanical ventilation [invasive or noninvasive] per day for > 21 consecutive days in the absence of an acute

reversible event)

Secondary outcome

Secondary endpoints:

Evaluate the effects of ION363 vs. placebo on change (or geometric mean ratio, as appropriate) from Baseline to Study Day 505 in Part 1 Cohorts A and B*on clinical assessments and biomarkers of disease severity, specifically the following endpoints:

• Geometric mean ratio from Baseline in serum neurofilament light chain (NfL)

• Change from Baseline in the in-clinic ALSFRS-R

• Change from Baseline in the in-clinic SVC

• Change from Baseline in handheld dynamometry (HHD)

• Change from Baseline in Amyotrophic Lateral Sclerosis Specific Quality of Life-Revised (ALSSQOL-R)

• Overall survival

• VAFS

• Geometric mean ratio from Baseline in CSF NfL

• Geometric mean ratio from Baseline in CSF FUS protein

Exploratory endpoints:

Evaluate the effects of ION363 vs. placebo on change from Baseline to Study Day 505 in Part 1 Cohorts A and B on the following endpoints:

• At-home ALSFRS-R total score

• At-home vital capacity

• King*s ALS Clinical Staging (King*s)

• Clinical Global Impression-Improvement (CGI-I) and Severity (CGI-S)

• Patient Global Impression-Improvement (PGI-I) and Severity (PGI-S)

• Center for Neurologic Study-Bulbar Function Scale (CNS-BFS)

• Speech-based analytics (Aural Analytics)

• Ventilation use

• Rate of *rescue* from Part 1

• Health-related quality of life (HRQoL) as measured by:

o Rasch-Built Overall Amyotrophic Lateral Sclerosis Disability Scale (ROADS)

o ALS Assessment Questionnaire, 5-item (ALSAQ-5)

o Fatigue Severity Scale (FSS)

o Zarit Burden Interview, 12-item (ZBI-12)

o EuroQol 5-Dimension 5-Level (EQ-5D-5L)

o Amyotrophic Lateral Sclerosis-Health Index (ALS-HI)

• Cognitive and behavioral functioning

o Edinburgh Cognitive and Behavioural ALS Screen (ECAS)

• Patient exit interview

• Disease biomarkers may include but are not limited to:

o CSF and serum neurofilament heavy chain (NfH)

o CSF YKL40 (also known as chitinase-3-like protein 1 [CHI3L1]), tau,

neurogranin, glial fibrillary acidic protein (GFAP), and pentraxins

o Plasma C-reactive protein

• Volumetric MRI, including whole brain and ventricles

Safety endpoints:

Safety and tolerability of ION363 will be assessed by determining the incidence

and severity of the following parameters:

• Treatment-emergent AEs, serious AEs and changes in concomitant medications

• Physical examination and neurological assessment

• Vital signs (body temperature, heart rate [HR], BP, weight, respiration)

• Electrocardiograms (ECGs)

• CSF safety labs (cell counts, protein, albumin, glucose)

• Laboratory tests (clinical chemistry, hematology, coagulation, urinalysis)

• Columbia - Suicide Severity Rating Scale (C-SSRS)

• Plasma anti-ION363 antibodies

• Worsening of disease biomarkers and clinical efficacy assessments that

exceeds what is expected from worsening of the underlying disease

• CSF and serum oligoclonal bands or free kappa index and immunoglobulin G

(IgG) collected at Baseline (and during study as indicated)

Clinical and CSF measures will be used to monitor for unexpected deterioration

Study description

Background summary

Amyotrophic lateral sclerosis is a fatal neurodegenerative disease pathologically characterized by aggressive deterioration of frontotemporal neurons, corticospinal tract, brainstem neurons, and anterior horn neurons (Statland et al. 2015). Patients suffer with loss of muscle mass, strength, and function in bulbar, respiratory, and voluntary muscle. Decline is inevitable, with death from respiratory failure following 2 to 5 years after diagnosis for most patients. Amyotrophic lateral sclerosis (ALS) associated FUS mutations are often associated with a more severe course compared to ALS patients associated with other genetic mutations.

Unfortunately, there is no effective treatment available for this form of ALS.
This study involves providing an investigational drug called ION363. ION363 is designed to reduce the body*s production of the FUS protein that may contribute to the ALS caused by a mutation in the FUS gene.

Study objective

This study has been transitioned to CTIS with ID 2024-512163-31-00 check the CTIS register for the current data.

Primary objective: To evaluate the clinical efficacy of ION363 in clinical functioning and survival in FUS-ALS patients.

Secondary objective: To further evaluate the effects of ION363 in halting, reversing, or slowing the deterioration of clinical functioning and biomarkers of disease severity in FUS-ALS patients.

Exploratory objective: To further evaluate the effects of ION363 in halting, reversing, or slowing the deterioration of clinical functioning and global health in FUS-ALS patients.

Safety objective: To evaluate the safety and tolerability of ION363 in FUS-ALS patients.

Study design

ION363-CS1 is a global, multicenter study of ION363 delivered by intrathecal (IT) bolus injection in adolescent and adult patients with, or developing, FUS-ALS.
The study consists of 3 parts: Part 1, a randomized, double-blind, placebo-controlled treatment period; Part 2, a treatment extension period; and Part 3, an additional open-label Treatment Period.

Part 1, Randomized, Double-blind, Placebo-controlled Treatment Period:
Part 1 is a multicenter, parallel-group, double-blind study of a single-dose regimen of 100 mg ION363 vs. placebo (randomized in a 2:1 ratio) delivered by lumbar IT bolus injection in adolescent and adult FUS mutation carriers with signs or symptoms of ALS who are >= 10 years of age. Part 1 consists of a Screening Period of up to 4 weeks, a Treatment Period of 60 weeks, and a Post-Treatment Follow-up Period of 12 or 40 weeks. After completing the Treatment Period a 12-week Post-Treatment Follow-up Period in Part 1, patients can enter Part 2. Patients who do not enter Part 2 will complete a 40-week Post-Treatment Follow-up Period in Part 1.

In Part 1, eligible patients will be assigned to either Cohort A, B, or C depending on their slow vital capacity (SVC), age, and ALS Functioncal Rating

(ALSFRS-R) pre-study slope.
- Cohort A will enroll FUS-ALS patients who have SVC >= 50% of predicted value and are 10 to 65 years of age (inclusive) at the time of informed consent. All eligible patients 10 to 29 years of age (inclusive) will enroll into Cohort A without regard to ALSFRS-R pre-study slope. Patients in Cohort A who are 30 to 65 years of age (inclusive) must have an ALSFRS-R pre-study slope >= 0.4 points per month. Cohort A will be stratified by age of onset of ALS symptoms: < 25 years (Strata 1; juvenile amyotrophic lateral sclerosis [JALS]) and >= 25 years (Strata 2; non-JALS).
- Cohort B will enroll FUS-ALS patients who have SVC >= 50% of predicted value and are >= 30 years of age at the time of informed consent. All eligible patients > 65 years of age will enroll into Cohort B without regard to ALSFRS-R pre-study slope. Patients in Cohort B who are 30 to 65 years of age (inclusive) must have an ALSFRS-R pre-study slope < 0.4 points per month.
- Cohort C will enroll up to 12 FUS-ALS patients who have SVC < 50% of predicted value, are 10 to 30 years of age (inclusive) at the time of informed consent, and had ALS symptom onset within 12 months before the time of informed consent. Patients in Cohort C have no ALSFRS-R pre-study slope criterion.

Enrollment in Part 1 will stop when the total number of patients in Cohorts A and B reaches 73, regardless of whether enrollment in Cohort C has reached 12 patients. Eligibility criteria thresholds are specified below for respiratory function and cognitive impairment symptom burden. Patients on a stable dose of riluzole, edaravone, and/or Relyvrio (sodium phenylbutyrate/taurursodiol combination, called Albrioza in Canada) will be permitted in the study.

Patients enrolled in Part 1 will receive 7 doses of Study Drug (ION363 or placebo). Study Drug will be administered every 12 weeks over the 60-week Treatment Period with an additional loading dose administered 4 weeks after the first dose. Doses will be administered via lumbar IT bolus on Study Days 1, 29, 85, 169, 253, 337, and 421.

Patients in Part 1 who experience a deterioration in total ALSFRS-R score to <15 points AND a decrease of >= 10 points from Baseline at Study Day 253, or later, that is confirmed, after an interval of at least 4 weeks may discontinue Part 1 and enter Part 2 of the study (refer to Section 3.8).

Part 2: Treatment Extension Period
Part 2 is a multicenter, 96 or 124-week period for patients from Part 1,and for patients from the Investigator-initiated study (IIS) that consists of an 84-week Treatment Period and a 12- or 40-week Post-treatment Follow-up Period. All patients entering Part 2 will receive open-label ION363 on Day 1 of Part 2. Patients coming from Part 1 may have received either ION363 or placebo in Part 1; ; those who received placebo in Part 1 would thus require a loading dose of ION363 at 4 weeks after their initial dose in Part 2. To maintain the blinding of Study Drug assignment in Part 1, patients from Part 1 will first enter a 4-week Loading Period in which they receive their second dose in Part 2 as

follows, in a double-blind manner: patients who received placebo in Part 1 will receive ION363 on Study Day 29 of Part 2 and patients who received ION363 in Part 1 will receive placebo on Study Day 29 of Part 2. Except for the loading dose on Study Day 29, ION363 will be administered open-label every 12 weeks during the 84-week Treatment Period (for a total of 9 doses of Study Drug during Part 2 for patients coming from Part 1).

For patients completing the 12-week Part 1 Post-treatment Follow-up Period, their first visit of Part 2 will align with Part 1 Study Day 505 to maintain a 12-week dosing interval. Patients who have been rescued (refer to Section 3.8) in Part 1 may enter Part 2 after confirmation of *rescue* status, with their initial administration of Study Drug in the Part 2 Treatment Period occurring 12 weeks after their last administration of Study Drug in Part 1.
Patients coming from the IIS all received ION363 in the IIS and will thus enter directly into the 84-week Open-Label Treatment Period in Part 2 and receive open-label ION363 every 12 weeks with no loading dose (for a total of 8 doses of ION363 during Part 2 for patients
coming from the IIS).
After the 84-week Part 2 Treatment Period, patients who are continuing to Part 3 will complete a 12-week Post-Treatment Follow-up Period, with the Part 3 Day 1 visit aligning with the Part 2 Day 673 visit, and patients who are not continuing to Part 3 will complete a 40-week Posttreatment
Follow-up Period (approximately 5 half-lives of the drug).

Part 3: Additional Open-Label Extension Period
Patients who complete the Part 2 Treatment Period are eligible to participate in Part 3 if ION363 is not commercially available in the patient*s country at that time. Patients may continue to receive open-label treatment in Part 3 for up to 3 additional years or until ION363 becomes commercially available in the patient*s country or until the Sponsor discontinues the development program, whichever occurs earlier. ION363 dosing in Part 3 will continue at clinic visits at 12-week intervals. For patients who terminate early from Part 3, there will be a Post-Treatment Follow-up Period of 40 weeks.

Intervention

Throughout the study, each dose of ION363 or placebo will be administered as a single 20 mL IT bolus injection.
Study Drug will be administered as a slow IT bolus injection (taking 1 to 3 minutes) using a *spinal anesthesia* needle and syringe. The target site for needle insertion is the L3/L4 space but may be 1 space above or 1 to 2 spaces below this level, if needed. Prior to the injection, an equal volume of CSF will be collected for analyses. Spinal ultrasound (or another imaging technique according to site practices) may be used for the LP procedure, if deemed necessary, but is not required. Local anesthesia may be used for the LP procedure, following institutional procedures.

Part 1: Patients will receive a total of 7 doses of Study Drug (ION363 or placebo). Study Drug will be administered every 12 weeks over the 60-week Treatment Period aside from a loading dose administered 4 weeks after the first dose.

Part 2: Patients entering Part 2 after completing or being rescued in Part 1 will receive open-label ION363 every 12 weeks and an additional blinded loading dose of Study Drug on Day 29 (ION363 for patients who had received placebo in Part 1, placebo for patients who had received ION363 in Part 1). Patients entering Part 2 from the IIS will receive open-label ION363 every 12 weeks without the additional loading dose.

Part 3: All patients for whom ION363 is not commercially available after Part 2 completion will receive ION363 at dosing intervals of 12 weeks for up to 3 years.

Study burden and risks

Based on preclinical data, there are currently no identified risks associated with ION363. Risks associated with the lumbar puncture (LP) procedure will be minimized by the use of atraumatic needles, aseptic procedures, exclusion of patients at increased risk of infection, herniation and loss of coagulation, and close patient monitoring after study drug administration. Patients will be closely monitored for signs and symptoms of neurologic effects.

Contacts

Public
Ionis Pharmaceuticals, Inc.

Gazelle Court 2855
Carlsbad CA 92010
US
Scientific
Ionis Pharmaceuticals, Inc.

Gazelle Court 2855
Carlsbad CA 92010
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Inclusion Criteria for Part 1
1. Must provide written informed consent (and assent, if indicated per patient*s age and institutional guidelines) (signed and dated) and any authorizations
required by local law
2. At the time of informed consent, a patient must be >10 years of age, and have signs or symptoms consistent with an ALS disease process (in the opinion of the Investigator)
3. Genetic mutation in FUS confirmed by a testing laboratory that is CLIA certified and CE-marked, or equivalent. Mutations must be reviewed and approved by a variant classification committee.
4. Upright (sitting position) SVC is >50% of predicted value (as adjusted for sex, age, and height) OR if SVC is < 50% of predicted value, must be 10 to 30 years of age (inclusive) at the time of informed consent AND had ALS symptom onset within 12 months before the time of informed consent
5. Able and willing to meet all study requirements (in the opinion of the Investigator), including travel to Study Center, procedures, assessments and visits
6. A patient who is taking edaravone, riluzole, Relyvrio (sodium phenylbutyrate/raurursodiol combination, called Abrioza in Canada), sodium phenylbutyrate, or tauroursodeoxycholic acid (TUDCA. also known as taurursodiol or urosodiol) must be on a stable dose for >= 28 days prior to Day 1, and willing to continue on that dose throughout the duration of the study, unless the Investigator determines that it should be discontinued for medical reasons, in which case it may not be restarted during the study
7. Satisfies the following:
a. A female must be not be pregnant or lactating and must fulfill one of the following:
i. is surgically sterile (e.g., hysterectomy, bilateral salpingectomy, bilateral oophorectomy, or vasectomized male partner)
ii. is postmenopausal (defined as no menses for 12 months without an

alternative medical cause). A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single FSH measurement is insufficient.
iii. is abstinent* or
iv. if engaged in sexual relations of childbearing potential, agree to use a highly effective contraceptive method (refer to Section 6.3.1 from the time of signing the ICF until at least 40 weeks after the last dose of Study Drug
b. A male must be abstinent*, surgically sterile (had a vasectomy with negative semen analysis at follow-up, or has a surgically sterile non-pregnant female partner), or if engaged in sexual relations with a woman of childbearing potential (WOCBP), agree to use a highly effective contraceptive method (refer to Section 6.3.1) from the time of signing the ICF until at least 40 weeks after the last dose of Study Drug
* Only true abstinence (i.e., abstinence in line with the preferred and usual lifestyle of the patient) is acceptable. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), declaration of abstinence for the duration of a trial and withdrawal are not acceptable methods of contraception.
8. Stable concomitant medications and nutritional support for at least 1 month prior to Study Day 1. Concomitant medications or nutritional support that have not been stable for at least 1 month prior to Study Day 1 may be allowed per Investigator judgement.
9. Has an informant/caregiver who, in the Investigator*s judgment, has frequent and sufficient contact with the patient to be able to provide accurate information about the patient's cognitive and functional abilities throughout the study. In addition, a patient who is < 18 years old must have a trial partner (parent, caregiver or other) who is reliable, competent, at least 18 years of age, and willing to accompany the patient to trial visits.

Inclusion Criteria for Part 2:
1. Completed, or was rescued from, Part 1, or enrolled and received at least 1 dose of ION363 in the Investigator-initiated study (ISS). Patients from the IIS must provide written informed consent (and assent, if indicated per patients' age and institutional guidelines) (signed and dated) and any authorizations required by law.
2. Satisfies the following:
a. A female must not be pregnant or lactating and must fulfill one of the following:
i. is surgically sterile (e.g., hysterectomy, bilateral salpingectomy, bilateral oophorectomy, or vasectomized male partner)
ii. is postmenopausal (defined as no menses for 12 months without an alternative medical cause). A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a postmenopausal state in women not using hormonal contraception or hormonal replacement therapy. However, in the absence of 12 months of amenorrhea, a single FSH measurement is

insufficient.
iii. is abstinent* or
iv. if engaged in sexual relations of childbearing potential, agree to use a highly effective contraceptive method (refer to Section 6.3.1 from the time of signing the ICF until at least 40 weeks after the last dose of Study Drug
b. A male must be abstinent*, surgically sterile (had a vasectomy with negative semen analysis at follow-up, or has a surgically sterile non-pregnant female partner), or if engaged in sexual relations with a woman of childbearing potential (WOCBP), agree to use a highly effective contraceptive method (refer to Section 6.3.1) from the time of signing the ICF until at least 40 weeks after the last dose of Study Drug
* Only true abstinence (i.e., abstinence in line with the preferred and usual lifestyle of the patient) is acceptable. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), declaration of abstinence for the duration of a trial and withdrawal are not acceptable methods of contraception.
3. Is suitable for study participation, in the opinion of the Investigator

Exclusion criteria

Exclusion Criteria for Part 1:
1. Requiring permanent ventilation (> 22 hours of mechanical ventilation [invasive or noninvasive] per day for > 21 consecutive days) or tracheostomy
2. Any known genetic variant (other than those in the FUS gene) that is pathogenic or likely to be pathogenic for the ALS-frontotemporal dementia (FTD) spectrum of disease
3. Positive test result for:
a. Human immunodeficiency virus (HIV)
b. Hepatitis C (HCV), unless previously treated and has been serum/plasma HCV RNA negative for at least 6 months after the end of treatment
c. Hepatitis B (HBV) by HBV surface antigen test, unless currently on nucleotide/nucleoside analogue treatment
4. Clinically significant abnormalities in medical history (e.g., previous acute coronary syndrome within 3 months before Screening, major surgery within 2 months before Screening) or physical examination
5. Active infection requiring systemic antiviral or antimicrobial therapy that will not be completed prior to Study Day 1.
6. Uncontrolled hypertension (blood pressure [BP] > 160/100 mmHg)
7. Malignancy within 1 year before Screening, except for basal or squamous cell carcinoma of the skin or carcinoma in situ of the cervix that has been successfully treated. Patients with a history of other malignancies that have been treated with curative intent and have not recurred within 6 months may also be eligible per Investigator judgement.
8. Obstructive hydrocephalus.
9. Presence of a functional ventriculoperitoneal shunt for the drainage of

cerebrospinal fluid (CSF) or an implanted central nervous system catheter.
10. Known significant brain or spinal disease that would interfere with the lumbar puncture (LP) procedure, CSF circulation or safety assessment, including tumors or abnormalities by magnetic resonance imaging (MRI) or computed tomography (CT), subarachnoid hemorrhage, suggestion of raised intracranial pressure on MRI or ophthalmic examination, spinal stenosis or curvature, chiari malformation, obstructive hydrocephalus, syringomyelia, tethered spinal cord syndrome and connective tissue disorders such as Ehlers-Danlos syndrome and Marfan syndrome
11. Presence of significant cognitive impairment, not due to a developmental disability, based on the Mini-Mental State Examination (MMSE) (score of < 20) or an equivalent assessment, clinical dementia, or unstable psychiatric illness, including psychosis, suicidal ideation, suicide attempt, or untreated major depression, as determined by the Investigator
12. Concurrent participation in any other interventional clinical study
13. Previous or current treatment with an oligonucleotide (including small interfering RNA [siRNA], tofersen). This exclusion criterion does not apply to coronavirus disease 2019 (COVID-19) vaccinations, which are allowed.
14. Treatment with another investigational drug, biological agent, or device, within 1 month before Screening or 5 half-lives of the investigational agent, whichever is longer.
15. History of gene therapy or cell transplantation or any other experimental brain surgery.
16. Anticipated need, in the opinion of the Investigator, for administration of any antiplatelet or anticoagulant medication that cannot be safely paused before and/or after an LP procedure according to local or institutional guidelines and/or Investigator determination after consultation with the appropriate treating physician. Low-dose aspirin (<= 100 mg/day, administered as monotherapy) is permitted and may be continued through the LP procedure.
17. Clinically significant low platelet count (defined as < 100,000/mm3), coagulation tests, or laboratory abnormalities that would render a patient unsuitable for inclusion
18. Unwillingness to comply with study procedures, including follow-up, as specified by this protocol, or unwillingness to cooperate fully with the Investigator
19. Has any other condition that would make the patient unsuitable for inclusion or could interfere with the patient participating in or completing the study, in the opinion of the Investigator

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	20-05-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-08-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-02-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den

	Haag)
Approved WMO Date:	20-03-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-10-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-10-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-03-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-07-2024
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	CTIS2024-512163-31-00
EudraCT	EUCTR2020-005522-28-NL
ClinicalTrials.gov	NCT04768972
CCMO	NL78827.000.22