A phase 3, multicenter, randomized, double-blind, placebo-controlled study of AG-881 in subjects with residual or recurrent grade 2 glioma with and IDH1 or IDH2 mutation

Published: 27-05-2020
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This study has been transitioned to CTIS with ID 2024-512961-15-00 check the CTIS register for the current data. Primary:• The primary objective of the study is to demonstrate the efficacy of vorasidenib based on radiographic progression-free...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON54490

Source
ToetsingOnline

Brief title
AG881-C-004

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Glioma

Research involving
Human

Sponsors and support

Primary sponsor: Institut de Recherches Internationales Servier I.R.I.S
Source(s) of monetary or material Support: Agios Pharmaceuticals;Inc.

Intervention

Keyword: Grade 2 Glioma, IDH1 mutation, IDH2 mutation, Vorasidenib

Outcome measures

Primary outcome

The primary endpoint is PFS, defined as the time from date of randomization to date of the first occurrence of radiographic PD by modified RANO-LGG assessed by the BIRC or death from any cause, whichever occurs earlier. Progression-free survival for subjects without centrally confirmed radiographic PD by RANO-LGG by the BIRC or death will be censored at the date of the last disease assessment. Censoring reasons also include start of a subsequent anticancer therapy, withdrawal of consent from overall study participation, and loss to follow-up.

The primary efficacy analysis will compare the PFS time between the 2 treatment arms using a 1-sided stratified log-rank test. The test will be stratified by 1p19q status and baseline tumor size. A Cox proportional hazards (PH) model stratified by randomization stratification factors will be used to estimate the hazard ratio of PFS, along with its 95% CI.

Assuming a median PFS of 18 months for the placebo arm and a median PFS of 30 months for the vorasidenib arm, a total of 164 PFS events are required to

provide at least 90% power to detect a hazard ratio of 0.6 at a 1-sided alpha of 0.025 level of significance using a log-rank test stratified by the randomization stratification factors, and a 3-look group sequential design with a Gamma family (-24) α-spending function to determine the efficacy boundaries and a Gamma family (-5) β-spending function to determine the nonbinding futility boundaries. Assuming a recruitment period of approximately 42 months, and a 10% dropout rate in PFS at 12 months, approximately 340 subjects will need to be randomized to the 2 treatment arms in a 1:1 ratio.

There are 3 planned analyses for PFS: an interim analysis for futility, an interim analysis for superiority, and a final analysis. A small alpha will be allocated to the PFS futility analysis based on the selected α-spending function. The interim analyses for PFS will be performed based on FAS and will take place after the target number of events has occurred as described below.

• Interim analysis 1 (IA1, futility only): will be conducted when approximately 55 PFS events (33.5% of the expected 164 events) have occurred

• Interim analysis 2 (IA2, superiority and futility): will be conducted when all subjects are randomized and approximately 123 PFS events (75% of the expected 164 events) have occurred.

• Final analysis (FA): will be conducted when all subjects are randomized and 164 PFS events have occurred.

Secondary outcome

Key secondary endpoint:

The key secondary endpoint is TTNI, defined as the time from randomization to

the initiation of the first subsequent anticancer therapy (including vorasidenib, for subjects randomized to placebo who subsequently cross over) or death due to any cause.

The secondary efficacy analysis will compare the TTNI between the 2 treatment arms using a 1-sided stratified log-rank test. The test will be stratified by 1p19q status and baseline tumor size. A Cox PH model stratified by randomization stratification factors will be used to estimate the hazard ratio of TTNI, along with its 95% CI.

The sample size of 340 subjects will also allow an assessment for TTNI assuming a 10% dropout rate for TTNI at 12 months. With an assumed median TTNI of 21 months for the placebo arm, a total of 152 TTNI events are required to provide approximately 80% power to detect a hazard ratio of 0.636 at a 1-sided alpha of 0.025 level of significance using a log-rank test stratified by the randomization stratification factors, and a 2-look group sequential design with a Gamma family (-22) α-spending function to determine the efficacy boundaries.

To control the overall type I error rate at the 1-sided 2.5% level, the fixed sequence testing procedure will be used to adjust for multiple statistical testing of the primary endpoint and key secondary efficacy endpoint TTNI. These endpoints will be tested in the following order:

• PFS per BIRC

• TTNI.

Other secondary endpoints:

Other secondary efficacy endpoints are TGR, objective response, CR+PR, time to

response, time to CR+PR, duration of response, duration of CR+PR, OS, FACT-Br scores, and PFS by investigator.

Safety:

Safety will be evaluated by the incidence, severity, and type of adverse events, and by evaluation of vital signs, KPS/LPPS, clinical laboratory results, electrocardiograms, and LVEF data (as clinically indicated). All data will be provided in by-subject listings. All safety data will be listed by subject and summarized by treatment arm based on the Safety Analysis Set.

Pharmacokinetics:

Descriptive statistics of plasma concentrations (arithmetic and geometric means, standard deviation, coefficient of variation [CV%], CV% geometric mean, minimum, median and maximum) of vorasidenib and its metabolite AGI-69460 will be summarized.

Study description

Background summary

There is a protein inside the cells called IDH (isocitrate dehydrogenase). There are two main types of IDH in the body, called IDH1 and IDH2. Abnormal changes in the protein (mutations) can be found in certain types of cancer including glioma.

When IDH1 and/or IDH2 is mutated, it produces an excess amount of a substance (2-HG). When 2-HG is present in excessive amounts, it results in changes within the cells, which may result in glioma. As part of pre-screening, the tumor tissue was tested to see if it was positive for IDH1 or IDH2 mutations. The subject will only be enrolled in this study and given AG-881 or placebo if the

tumor tissue is positive for mutation in IDH1 or IDH2 and the subject meets the other inclusion criteria required.

AG-881 is a new investigational drug in development by the Sponsor to potentially treat patients with glioma. AG-881 is a drug that is designed to block the abnormal IDH1 and IDH2 protein in cancer cells. Investigational means that AG-881 has not been approved for use either alone or in combination with any drug by any health authority. AG-881 may stop the abnormal IDH1 and/or IDH2 protein and lower the level of 2-HG.

Study objective

This study has been transitioned to CTIS with ID 2024-512961-15-00 check the CTIS register for the current data.

Primary:
• The primary objective of the study is to demonstrate the efficacy of vorasidenib based on radiographic progression-free survival (PFS) per blinded independent review committee (BIRC) compared with placebo in subjects with residual or recurrent Grade 2 oligodendroglioma and astrocytoma with an IDH1 or IDH2 mutation who have undergone surgery as their only treatment.
Key Secondary:
• To demonstrate the efficacy of vorasidenib based on time to next intervention (TTNI) compared with placebo.
Other Secondary:
• To evaluate the safety and tolerability of vorasidenib
• To evaluate vorasidenib and placebo with respect to tumor growth rate (TGR) as assessed by volume per the BIRC.
• To evaluate the efficacy of vorasidenib and placebo based on objective response, complete response (CR) + partial response (PR), time to response, time to CR+PR, duration of response, and duration of CR+PR with response assessed per the BIRC and the Investigator.
• To evaluate vorasidenib and placebo with respect to overall survival (OS).
• To evaluate vorasidenib and placebo with respect to health-related quality of life (HRQoL) as assessed by the Functional Assessment of Cancer Therapy - Brain (FACT-Br) questionnaire.
• To evaluate vorasidenib and placebo with respect to PFS per the Investigator assessment.
• To evaluate the pharmacokinetics (PK) of vorasidenib and its circulating metabolite AGI-69460 in plasma.
Exploratory:
• To evaluate, for subjects who cross over from placebo to vorasidenib, the time from first dose of vorasidenib to documented progression on vorasidenib, as assessed by the Investigator or death due to any cause, whichever occurs first.
• To evaluate TGR before and after treatment with vorasidenib among subjects who cross over from placebo to vorasidenib.

• To evaluate HRQoL with vorasidenib and placebo as assessed by the EuroQol 5 Dimensions 5 Level (EQ-5D-5L) questionnaire and Patient Global Impression (PGI) questions.
• To evaluate neurocognitive function in subjects receiving vorasidenib and placebo as assessed by a validated battery of cognitive performance instruments.
• To evaluate seizure activity in subjects receiving vorasidenib and placebo.
• To evaluate the molecular and cellular markers that may be predictive of response and/or resistance, where feasible, in blood and archival tumor tissue.
• To evaluate TGR before and after treatment with vorasidenib and placebo.
• To evaluate time to malignant transformation and radiographic changes associated with histopathology-proven malignant transformation in subjects who have surgery or biopsy as an intervention.

Study design

Subjects who meet all study eligibility criteria will be randomly assigned in a 1:1 ratio to receive AG 881 orally at a dose of 40 mg once daily (QD) or AG-881-matched oral placebo QD. Randomization will be stratified by local 1p19q status (co-deleted or not co-deleted) and baseline tumor size per local assessment (longest diameter of >=2 cm or <2 cm). Starting with Cycle 1 Day 1 (C1D1), dosing is continuous; there are no planned intercycle rest periods.
A BIRC will assess radiographic eligibility for study entry, the primary efficacy endpoint of radiographic PFS per modified Response Assessment for Neuro-Oncology for Low-Grade Gliomas (RANO-LGG) criteria, and the secondary efficacy endpoint of TGR as assessed by tumor volume. The BIRC will also be used to confirm radiographic disease progression (PD) by the Investigator to permit unblinding and crossover. Radiographic disease assessment (by magnetic resonance imaging [MRI]) for evaluation of disease response will be conducted at specified time points throughout the study or at any time PD is suspected. Target lesion selection and tumor response per RANO LGG criteria will be performed by the institutional radiologist/Investigator. Scan acquisition parameters required per protocol will be detailed in a separate site-specific imaging core manual. All MRI scans will be sent to the BIRC as detailed in the site-specific Imaging Core Manual.
Subjects who discontinue study treatment for reasons other than centrally confirmed radiographic PD by the BIRC or withdrawal of consent from treatment and overall study participation (and not just study treatment) will be followed in PFS Follow-up until documented radiographic PD by BIRC or the initiation of new anticancer therapy. Overall Survival Follow-up assessments will occur approximately 6 months (±4 weeks) after End of Treatment (EOT). For subjects in PFS Follow-up, OS Follow-up will begin once PFS Follow-up has ended. Overall Survival Follow-up will continue for up to 5 years after the last subject is randomized or until all subjects have died, withdrawn consent from overall study participation, or are lost to follow-up or the Sponsor ends the study, whichever occurs first.

Intervention

Investigational Product, Dosage, and Mode of Administration:
AG-881 40 mg QD will be taken orally by the subject on Days 1 to 28 in 28-day cycles. Dosing is continuous; there are no planned intercycle rest periods.

Reference Therapy, Dosage, and Mode of Administration:
AG-881-matched placebo 40 mg QD will be taken orally by the subject on Days 1 to 28 in 28-day cycles. Dosing is continuous; there are no planned intercycle rest periods.

Approximately 340 subjects are planned to be randomized 1:1 to receive AG-881 or AG-881-matched placebo.

Study burden and risks

What side effects or risks can I expect from being in the study?
You may have side effects while taking part in the study. Everyone taking part in the study will be carefully monitored for any side effects. Since the study drug is investigational, there may be other risks that are unknown. You should talk to your study doctor if you have any side effects during the study or if you want more information about the side effects.

Certain side effects are known to be caused by the use of vorasidenib
Abnormal liver tests (very common, occurred in 10% or greater)
Vorasidenib may affect your liver function. Your study doctor will check your liver function with blood tests before you start taking vorasidenib and during study treatment. It is important to tell your study doctor or site staff if you have any liver disease.

Certain risks that may be caused by vorasidenib
Abnormal Heartbeat (an abnormal electrical condition of the heart (QT Prolongation)) (common, occurred in 1% to less than 10%):
Vorasidenib alone or in combination with other certain drugs may cause changes in the electrical activity of your heart. This change can cause irregular heartbeats that can be life threatening. Your study doctor will do tests before you start taking vorasidenib and during your study treatment with vorasidenib to check the electrical activity of your heart. Other medications taken with vorasidenib may increase your risk of an abnormal heartbeat, so be sure your study doctor is aware of all medications, including over-the-counter medications and dietary supplements, that you are taking at all times. Tell your study doctor right away if you feel new chest pain or discomfort, dizziness, or light headedness or if you feel faint.

Gastrointestinal disorders
Some animals given very high doses of vorasidenib developed ulcers of the

stomach and intestine. Similar events have not been seen in human subjects taking vorasidenib. Inform your study doctor if you develop abdominal pain, heartburn, nausea, or vomiting as these could be symptoms of a gastrointestinal ulcer.

Nerve disorders
Animals given high doses of vorasidenib developed neurological disturbances including, shaking (similar to tremors),impaired balance or coordination and head tilt (holding head or neck in a twisted or otherwise abnormal position). Inform your study doctor if you develop any similar neurological disturbance symptoms.

Skin disorders
Animals receiving high doses of vorasidenibdeveloped skin peeling. Skin peeling events have not been seen in human subjects taking vorasidenib. Inform your study doctor if you develop any changes in your skin.

IDH Differentiation Syndrome
IDH Differentiation Syndrome is a condition that may include one or more of the following symptoms: unexplained fever, shortness of breath, high white blood cell counts (blood cells that fight infection), high platelet counts (blood cells that help with clotting), and/or fluid in or around the lungs or heart. You may require further medical intervention. Until now, this side effect was only seen in patients with advanced blood cancer. The occurrence of IDH differentiation syndrome side effect is very common in advanced blood cancer subjects (occurred in 10% or greater) but has not occurred in any solid tumor subjects.

Vorasidenib with other medications
You will be provided with a diary so that you can record details around taking your study drug at home. It is important to fill out the diary and bring it with you to every visit.

As the study goes on, if new risks are identified with vorasidenib, you will be made aware of these risks by the study doctor or site staff and may be asked to sign a new informed consent form.

The effects of vorasidenib when combined with medications, food, or alcohol are not all known. Vorasidenib may change the amount of other drugs in your body or the drugs you are taking may change the amount of vorasidenib in your body. Please discuss with your study doctor the use of alcohol or any drugs (over the counter, prescription, illegal) you are taking prior to taking vorasidenib.

Other Potential Risks Not Related to the Study Drug
Genetic testing
This research includes genetic testing. To protect your privacy, your genetic

samples are coded. But even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracking information.
There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information.

Blood Drawing
During this study, small amounts of blood will be drawn from a vein to perform tests that allow your study doctors to check how you are doing and to measure the amounts of certain substances in your blood. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising and/or infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn.

MRI
If you have metal or electronic devices in your body such as heart pacemakers, implantable defibrillators, artificial limbs, or metal implants, you must notify your study doctor prior to the MRI scans. The magnet of the MRI can cause damage to the devices and the devices/ implants will distort the images. You may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia).
At some point during the MRI scan, the scanning procedure will be interrupted so that you can be given a contrast agent through a needle in your arm. There is a very minimal risk of discomfort, tingling or warmth in the lips, a metallic taste in the mouth, tingling in the arm, nausea, and/or headache. If these symptoms occur, these symptoms go away quickly. There is also a slight risk of allergic reaction, vomiting, itching, and/or rash. The contrast agents may also cause problems in subjects with kidney disease.

Biopsy Collection
A biopsy collection will require that you be hospitalized, and the procedure is performed while you are under anesthesia. Risks associated with tumor biopsy include pain, swelling, bleeding or blood clot formation, epileptic seizure, bruising, infection, or reaction to anesthesia. Your study doctor, or site staff, will complete a detailed review of the risks related to a tumor biopsy with anesthesia and may ask you to sign a separate consent form related to this procedure.

ECG
You may have mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

Contacts

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Scientific
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Route 128 22
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Be at least 12 years of age and weigh at least 40 kg.
3. Have Grade 2 oligodendroglioma or astrocytoma per WHO 2016 criteria.
4. Have had at least 1 prior surgery for glioma (biopsy, sub-total resection, gross-total resection), with the most recent surgery having occurred at least 1 year (-1 month) and not more than 5 years (+3 months) before the date of randomization, and no other prior anticancer therapy, including chemotherapy and radiotherapy and not be in need of immediate chemotherapy or radiotherapy in the opinion of the Investigator.
5. Have confirmed IDH1 (IDH1 R132H/C/G/S/L mutation variants tested) or IDH2 (IDH2 R172K/M/W/S/G mutation variants tested) gene mutation status disease by

central laboratory testing during the Prescreening period and available 1p19q status by local testing (eg, fluorescence in situ hybridization [FISH], comparative genomic hybridization [CGH] array, sequencing) using an accredited laboratory.
6. Have MRI-evaluable, measurable, non-enhancing disease, as confirmed by the BIRC, assessed at Screening on 2D T2-weighted or 2D T2-weighted fluid-attenuated inversion recovery (FLAIR) MRI with <=4 mm slice thickness and no interslice gap. Measurable non-enhancing disease is defined as at least 1 target lesion measuring >=1 cm × >=1 cm (bidimensional). Centrally confirmed, minimal, non-nodular, and non-measurable enhancement that has not changed between the 2 most recent scans (including screening scan) will be permitted.
7. Have a KPS (Appendix 11.7) score (for subjects >=16 years of age) or LPPS (Appendix 11.6) score (for subjects <16 years of age) of >=80%.
8. Have expected survival of >=12 months.
9. Have adequate bone marrow function
10. Have adequate hepatic function
11. Have adequate renal function
12. Have recovered from any clinically relevant toxicities associated with any prior surgery for the treatment of glioma unless stabilized under medical management.

For the complete and extended list, see protocol section 4.2 Inclusion Criteria

Exclusion criteria

1. Have had any prior anticancer therapy other than surgery (biopsy, sub-total resection, gross-total resection) for treatment of glioma including systemic chemotherapy, radiotherapy, vaccines, small-molecules, IDH inhibitors, investigational agents, laser ablation etc.
2. Have features assessed as high-risk by the Investigator, including brainstem involvement either as primary location or by tumor extension, clinically relevant functional or neurocognitive deficits due to the tumor in the opinion of the Investigator (deficits resulting from surgery are allowed), or uncontrolled seizures (defined as persistent seizures interfering with activities of daily life AND failed 3 lines of antiepileptic drug regimens including at least 1 combination regimen).
3. Concurrent active malignancy except for a) curatively resected nonmelanoma skin cancer or b) curatively treated carcinoma in situ. Subjects with previously treated malignancies are eligible provided they have been disease-free for 3 years at Screening.
4. Are pregnant or breastfeeding.
5. Have an active infection that requires systemic anti-infective therapy or with an unexplained fever >38.5°C within 7 days of C1D1.
6. Have a known hypersensitivity to any of the components of AG-881.
7. Have significant active cardiac disease within 6 months before the start of

study treatment, including New York Heart Association Class III or IV congestive heart failure (Appendix 11.2), myocardial infarction, unstable angina, and/or stroke.
8. Have LVEF <40% by echocardiogram (ECHO) (or by other methods according to institutional practice) obtained within 28 days before the start of study treatment.
9. Have a heart-rate corrected QT interval using Fridericia*s formula (QTcF) >=450 msec or other factors that increase the risk of QT prolongation or arrhythmic events (eg, heart failure, hypokalemia, family history of long QT interval syndrome). Subjects with bundle branch block and prolonged QTcF are permitted with approval of the Medical Monitor.
10. Are taking therapeutic doses of steroids for signs/symptoms of glioma. Subjects taking physiologic doses (defined as equivalent of <=10 mg prednisone daily) for medical conditions not related to glioma will be permitted.
11. Exclusion Criterion 11 removed in Protocol Amendment 1 (v2.0).
12. Are taking any medications that are CYP3A or CYP2C9 substrates with a narrow therapeutic index as listed in Appendix 11.4. (Subjects should be transferred to other medications before receiving the first dose of study drug.)
13. Have known active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection, known positive human immunodeficiency virus antibody results, or AIDS-related illness. Subjects with a sustained viral response to HCV treatment or immunity to prior HBV infection will be permitted. Subjects with chronic HBV that is adequately suppressed by institutional practice will be permitted.
14. Have known active inflammatory gastrointestinal disease, chronic diarrhea, previous gastric resection or lap band dysphagia, short-gut syndrome, gastroparesis, or other condition that limits the ingestion or gastrointestinal absorption of drugs administered orally. Gastroesophageal reflux disease under medical treatment is allowed (assuming no drug interaction potential).
15. Have any other acute or chronic medical or psychiatric condition, including recent (within 12 months of C1D1) or active suicidal ideation or behavior, or a laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the Investigator, would make the subject inappropriate for entry into this study.

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:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	32
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Vorasidenib (10 mg)
Generic name:	AG-881 (10 mg)
Product type:	Medicine
Brand name:	Vorasidenib (40 mg)
Generic name:	AG-881 (40 mg)

Ethics review

Approved WMO Date:	27-05-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-10-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-05-2021

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-07-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-08-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-12-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-03-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-11-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-12-2023
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
EU-CTR	CTIS2024-512961-15-00
EudraCT	EUCTR2019-002481-13-NL
ClinicalTrials.gov	NCT04164901
CCMO	NL73641.056.20