A Phase 1b/2a, Open Label Trial Evaluating the Safety, Pharmacokinetics, and Efficacy of EP-104IAR in Adults with Eosinophilic Esophagitis (RESOLVE)

Published: 26-07-2022
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This study has been transitioned to CTIS with ID 2024-516689-13-00 check the CTIS register for the current data. The primary objectives of this study are:• To determine the safety, tolerability, and RP2D(s) and regimen(s) of EP 104IAR• To determine...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON56323

Source
ToetsingOnline

Brief title
A study of EP-104IAR in Adults with Eosinophilic Esophagitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
Digestive system disorder, Swelling of esophagus

Research involving
Human

Sponsors and support

Primary sponsor: Eupraxia Pharmaceuticals Inc.

Source(s) of monetary or material Support: Eupraxia Pharmaceuticals Inc.

Intervention

Keyword: Adults, Eosinophilic Esophagitis, Fluticasone propionate, Intra-Articular injections

Outcome measures

Primary outcome

Safety

• Frequency and severity of treatment-emergent adverse events (TEAEs)

• Change from baseline in clinical safety laboratory measurements at Weeks 4

and 12

• Change from baseline in morning serum cortisol levels 24 hours postdose and

at Weeks 2, 4, 8, 12, and 24 and Week 52 for participants who receive >40 mg

total dose

• Change from baseline in vital signs at 1 and 24 hours postdose and at Weeks

2, 4, 8, 12 and physical examination results at Weeks 2, 4, 8, 12

Pharmacokinetics:

• Plasma concentrations of FP, measured at baseline (predose), 2 and 24 hours

postdose, and at Weeks 2, 4, 8, 12, 24, and Weeks 36 and 52 for participants

who receive >40 mg total dose.

Secondary outcome

Efficacy:

• Histological response mapped over the surface of the esophagus as a function

of proximity to, and size of dose, measured by peak eosinophil count (PEC) at

Weeks 4 and 12 and at Week 36 for participants who receive >40 mg total dose.

• Change from baseline in the Straumann Dysphagia Index (SDI) patient-reported outcome (PRO) score at Weeks 2, 4, 8, 12, 24, and Weeks 36 and 52 for participants who receive >40 mg total dose.

• Change from baseline in dysphagia measured on an 11 point Likert scale at Weeks 2, 4, 8, 12, 24, and Week 36 and 52 for participants who receive >40 mg total dose

• Change from baseline in odynophagia measured on an 11 point Likert scale at Weeks 2, 4, 8, 12, 24, and Week 36 and 52 for participants who receive >40 mg total dose

• Change from baseline in the EoE Endoscopic Reference Score (EREFS) at Weeks 4 and 12, and at Week 36 for participants who receive >40 mg total dose.

• Change from baseline in EoE Histology Scoring System (EoEHSS) score at Weeks 4 and 12, and at Week 36 for participants who receive >40 mg total dose.

Study description

Background summary

Eosinophilic esophagitis (EoE) is a rare, chronic, immune-mediated disease that is characterized by inflammation and the accumulation of large numbers of eosinophils within the epithelial lining of the esophagus.

The investigational medicinal product (IMP), EP-104IAR (long-acting fluticasone propionate [FP] injectable suspension), is being developed to treat pain and inflammation in patients diagnosed with EoE. EP-104IAR is intended to release drug steadily at the injection site, maintaining local site concentrations while minimizing systemic exposure to FP.

The active ingredient in EP-104IAR, FP, is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity. It has high selectivity

for the glucocorticoid receptor and has little activity at other steroid receptors. FP is more lipophilic than budesonide and triamcinolone acetonide (TCA) and has one of the highest affinities for the glucocorticoid receptor and lowest rate of dissociation. In vitro tests for anti-inflammatory activity have demonstrated that FP is more potent than other corticosteroids, e.g., beclomethasone dipropionate, budesonide, TCA, and mometasone furoate. Animal studies of systemic responses to various corticosteroids have shown FP to be less potent, or equipotent, compared to beclomethasone dipropionate, fluocinolone acetonide, and betamethasone alcohol in its ability to elicit thymus involution, hypothalamicpituitary-adrenal axis suppression, and/or adrenal atrophy. FP has known pharmacologic activity, absorption, distribution, metabolism, excretion, and side effects when given as an inhaled product.

Fluticasone propionate is currently approved by the US FDA, EMA, Health Canada, and other regulatory agencies to treat inflammatory effects associated with asthma, COPD, rhinitis, and dermatological disorders.

EP-104IAR is also currently in development to treat pain in patients diagnosed with osteoarthritis (OA). A Phase 2 clinical study is underway to evaluate the safety and efficacy of a single dose of 25 mg EP-104IAR in patients with OA of the knee.

Study objective

This study has been transitioned to CTIS with ID 2024-516689-13-00 check the CTIS register for the current data.

The primary objectives of this study are:
• To determine the safety, tolerability, and RP2D(s) and regimen(s) of EP 104IAR
• To determine the pharmacokinetic (PK) profile of EP-104IAR

A secondary/exploratory objective is:
• To evaluate the efficacy of EP-104IAR on eosinophilic esophagitis (EoE) disease activity as measured by
symptoms, endoscopy, and histology

Study design

EP-104IAR-102 is a Phase 1b/2a, open-label, multicenter, dose escalation study designed to explore multiple types of outcomes, including clinical safety, PK, endoscopic, and histologic. Both endoscopic and histologic assessments will be scored centrally. Approximately 27 to 33 adult participants with a history of histologically confirmed EoE with active symptoms (patient-reported) are planned to be enrolled in the dose escalation of this study. An additional 10-24 participants will be enrolled in 1 or 2 dose confirmation cohorts at tolerable dose(s) to identify the recommended RP2D(s).

At the Baseline (Visit 2), Week 4 (Visit 5), and Week 12 visits (Visit 7), or at early discontinuation (ED), all participants will undergo an esophagogastroduodenoscopy (EGD) with esophageal biopsies for endoscopic and histologic assessment. Additionally, participants who receive >40 mg total dose will undergo EGD with esophageal biopsies at Week 36. For regimens of 4-16 injections, a total of 16 biopsy specimens will be obtained from 8 different heights along the esophagus in a quadrant-like manner. The number of biopsies will be increased to 20 (at 10 heights in the esophagus) for regimens of 20 injections. Participants will complete paper questionnaires at clinic visits to assess symptoms of dysphagia and odynophagia. Safety will be assessed throughout the study, and blood samples will be collected for safety and PK assessments of EP-104IAR.

Dose escalation (and de-escalation):
Participants will be dosed in cohorts of 3 participants each. The initial cohort of 3 participants will receive submucosal injections of 1 mg EP-104IAR at 4 different sites providing a total administered dose of 4 mg EP 104IAR.

Dose escalation (or de-escalation) in subsequent cohorts will be determined by the Safety Monitoring Committee (SMC) using a modification of the traditional 3+3 oncology design. Dose escalation (or de-escalation) is permitted such that in each step, one of the following 2 axes may be increased: the number of injection sites; and the dose injected per site. Both axes may be changed in one escalation, providing only one axis is increased e.g. an increased dose per site at a lower number of injection sites. The SMC will determine whether each of the dose escalation regimens are allowable following review of safety data provided. The SMC may alternatively recommend dose escalation (or de-escalation) to an intermediate dose not shown in Table A. For an intermediate dose escalation, e.g. to 5 mg/site, the total dose will not exceed that which would be achieved by a permissible dose escalation step shown in Table A. The Sponsor will select the dose regimen for the next cohort based on the SMCs determination. Details of the possible dosing regimens are presented in Table A.

Table A: Possible dose regimens and total administered dose.

1
mg/site 2,5 mg/site 4
mg/site 6 mg/site
Number of injections of EP-104IAR Total Dose Total Volume Total Dose Total Volume Total Dose Total Volume Total Dose Total Volume
4 injection sites 4 mg 4 ml
10 mg 4 ml 16 mg 4 ml 24
mg 4 ml
8 injection sites 8 mg 8 ml
20 mg 8 ml 32 mg 8 ml 48
mg 8 ml

12 injection sites 12 mg 12 ml 30
mg 12 ml 48 mg 12 ml 72
mg 12 ml
16 injection sites 16 mg 16 ml 40
mg 16 ml 64 mg 16 ml 96
mg 16 ml
20 injection sites 20 mg 20 ml 50
mg 20 ml 80 mg 20 ml 120
mg 20 ml

Across all dose levels, the volume administered per injection site is 1 mL; the EP-104IAR Powder is constituted to concentrations of 1 mg/mL, 2.5 mg/mL, 4 mg/mL, or 6 mg/mL to meet dose requirements.

The maximum dose of EP-104IAR that could be administered per injection site is 2.5 mg. The maximum total dose of EP-104IAR that could be administered is 120 mg.

The dose-limiting toxicity (DLT) evaluation period is 4-weeks post injection. Upon review of the 4-week data for each cohort of 3 participants, the following rules will be followed:
• If zero participants exhibit a DLT (see definitions below), then dose escalation is permitted in the next cohort.
• If 1 of the 3 participants exhibits a systemic DLT or 1 of the 3 participants exhibits a local DLT, then a second cohort of 3 participants will be dosed with the same dose regimen. Of the 6 total participants at this dose:
o If there was a total of 1 (of 6) systemic DLT:
* Escalation is permitted, absent any restrictions from local DLTs.
o If there were 2 (of 6) or more systemic DLTs:
* Escalation of the total dose is complete.
* Further cohorts may study any other dosing strategies from Table A or intermediate dose level(s) recommended by the SMC e.g. 5 mg/site not shown in Table A, that have a total dose lower than the current cohort.
* Absent any local DLTs, there is no cap on the dose per-site (except as described in Table A).
o If there was a total of 1 (of 6) local DLT:
* Escalation is permitted, absent any restrictions from systemic DLTs.
o If there were 2 (of 6) or more local DLTs:
* Escalation of the per-site dose is complete.
* Further cohorts may study any other dosing strategies from Table A or intermediate dose level(s) recommended by the SMC e.g. 5 mg/site not shown in Table A, that have a per site dose lower than the current cohort.
* Absent any systemic DLTs, there is no cap on number of sites (except as described in Table A).
• If 2 or more (of 3) participants exhibit a systemic DLT:
o Escalation of the total dose is complete.

o Further cohorts may study any other dosing strategies from Table A, or intermediate dose level(s) recommended by the SMC e.g. 5 mg/site not shown in Table A, that have a total dose lower than the current cohort.
o Absent any local DLTs, there is no cap on the dose per-site (except as described in Table A).
• If 2 or more (of 3) participants exhibit a local DLT:
o Escalation of the per-site dose is complete.
o Further cohorts may study any other dosing strategies from Table A, or intermediate dose level(s) recommended by the SMC e.g. 5 mg/site not shown in Table A, that have a per-site dose lower than the current cohort.
o Absent any systemic DLTs, there is no cap on the number of sites (except as described in Table A).

When dose escalation is permitted:
• The decision (absent any restrictions from the above algorithm) to increase either the number of sites or dose per-site may be made on the basis of histological, PK, and safety data.
• At no point may a dose escalation step increase from a previously studied cohort by more than 1 row or column of the 2 axes shown in Table A (number of injection sites; and the dose injected per site) at a time, and only one axis may be increased per dose escalation step. Both axes may be changed in one escalation, providing only one axis is increased e.g. an increased dose per site at a lower number of injection sites.
• After each cohort, systemic PK will be predicted for future doses under consideration in the next cohort. A future dose with a predicted area under the curve from time zero to 4 weeks (AUC0-4weeks) > 3 ng•day/mL is not permitted.

Based on their review of safety data, the SMC may recommend dose de-escalation to an intermediate dose or regimen below the current dose, but not explored previously during dose es

Intervention

At Baseline, participants will undergo an upper EGD in combination with treatment administration where participants will receive submucosal injections of EP-104IAR.Administration of the IMP will be given in the clinic. All participants will be observed for at least 2 hours following treatment administration.

Table A: Possible dose regimens and total administered dose.

1
mg/site 2,5 mg/site 4
mg/site 6 mg/site
Number of injections of EP-104IAR Total Dose Total Volume Total Dose Total Volume Total Dose Total Volume Total Dose Total Volume
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mg 4 ml
8 injection sites 8 mg 8 ml
20 mg 8 ml 32 mg 8 ml 48
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mg 12 ml
16 injection sites 16 mg 16 ml 40
mg 16 ml 64 mg 16 ml 96
mg 16 ml
20 injection sites 20 mg 20 ml 50
mg 20 ml 80 mg 20 ml 120
mg 20 ml

Across all dose levels, the volume administered per injection site is 1 mL; the EP-104IAR Powder is constituted to concentrations of 1 mg/mL, 2.5 mg/mL, 4 mg/mL, or 6 mg/mL to meet dose requirements.

The maximum dose of EP-104IAR that could be administered per injection site is 2.5 mg. The maximum total dose of EP-104IAR that could be administered is 120 mg.

Study burden and risks

Risks associated with EP-104IAR:
The main ingredient in study medication is fluticasone propionate. Fluticasone propionate is a type of drug called a corticosteroid. Participants allergic to any corticosteroids, or any of the ingredients in study medication, cannot take part in this study.

The ingredients of study medication (fluticasone propionate and polyvinyl alcohol) have been used in people individually for a long time. But they have only been used together as EP-104IAR and injected in approximately 183 people with knee osteoarthritis. The most frequently reported side effects in the previous study were common cold, influenza, stomach flu, headache, and arthralgia (pain in a joint). No serious risks related to EP-104IAR were identified. EP-104IAR is also being tested in another ongoing study in 300 participants with knee osteoarthritis. If any new information from this study becomes available while you are taking part in this study, the study doctor will tell you about it.

When fluticasone propionate is taken through the nose or by inhaling, side effects such as a hoarse voice, fungus in the mouth (oral candidiasis), asthma, lung and sinus infections, sore throat, cough, bronchitis, and headache have been reported. If you have low thyroid hormone levels (hypothyroidism) or liver disease (cirrhosis), you could have more side effects from fluticasone

propionate.

As EP-104IAR contains a corticosteroid, it may have similar risks to other corticosteroid drugs. Not all patients will develop side effects from corticosteroids. How often any side effect occurs varies from person to person and depends on the dose, type of corticosteroid, how it is taken and the length of treatment. Some side effects are more serious than others. As EP-104IAR has only been used in a small number of people, it is not known how likely or unlikely it is that you might have one or more of these side effects.

Using corticosteroids together with other medications may result in drug-drug interactions (DDIs). DDIs occur when taking 2 (or more) drugs together results in possible changes to the effects (both good and bad) of 1 or both drugs and can potentially cause certain side effects.
When taking corticosteroids, you may have interactions with other medications.
• The use of medications that are strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) is not recommended because increased systemic corticosteroid side effects may occur (meaning side effects affecting the entire body).
• Vaccines are products that trains a person*s immune system to fight a certain disease it has not come into contact with before by mimicking the infectious bacteria or viruses that cause the disease. Vaccines are designed to prevent disease, rather than treat a disease once you have
caught it. Corticosteroids may prevent your body's immune system from responding correctly to the vaccine. Corticosteroids may lower your body's resistance and the vaccine may not work as well or you might get the illness the vaccine was supposed to prevent.

Possible side effects of corticosteroids in the body outside of the esophagus: There may be a temporary elevation of blood sugar which can trigger or worsen diabetes. For people with high blood pressure, there may be temporary elevated blood pressure. Injection of a corticosteroid is sometimes associated with a flushing reaction of the face and upper body, glaucoma (elevated pressure in the eyes), cataract formation (clouding in the lens on one or both eyes), fluid retention causing swelling the legs, mood changes, and insomnia.

Rarely, corticosteroid injections have been associated with a temporary feeling of numbness and weakness in the limbs. Also rarely, corticosteroid injections have been associated with conditions limiting the body*s ability to fight infections or deal with stressful situations (e.g., during surgery or illness), causing low blood pressure, changes in weight and fat deposits, or an allergic reaction. These rare events could possibly be life threatening.

Possible side effects of injected corticosteroids specific to the esophagus are currently unknown.

Risks associated with study procedures/tests:

Blood sample collection
• Pain, bruising and/or bleeding where the needle enters your vein.
• Some people feel light-headed or faint.
• In rare cases, blood taking can lead to swelling and/or infection of the vein.

Pregnancy test
Pregnancy tests may find a pregnancy you did not know about.

HIV test
HIV testing may find HIV infections you did not know about.

Urinalysis
Urine testing may find an infection or evidence of an underlying health condition you did not know about.

ACTH stimulation test
Side effects usually occur within 30 minutes after the ACTH injection and include:
• Pain, bruising and/or bleeding where the needle enters your muscle or vein.
• Nausea, vomiting, anxiety, sweating, dizziness, fast or irregular heartbeat, and facial flushing.
• Itchy skin, redness and swelling and/or infection at injection site.
• Feel light-headed or fainting, headache, severe dizziness, blurred vision, rash, severe swelling of face, lips, tongue, or other parts of the body, trouble breathing, and irregular heartbeat (rare)
• Allergic reactions (rare)

Esophagogastroduodenoscopy (EGD)
• Sore throat (common).
• Persistent bleeding after biopsy (if taken) (less common).
• Side effects such as drowsiness following sedative or pain medication (less common) or aspiration pneumonia, which is infection of the lungs (very rare).
• Perforation (a hole) of the esophageal muscle (rare). Surgery may be needed if a perforation occurs (rare).

EP-104IAR injection
There may be minor bleeding, infection, and perforation (a hole) of the esophageal muscle associated with the injections.

Esophageal biopsy
• Persistent bleeding after biopsy or polyp removal (if taken) can occur.
• Up to 16 samples will be taken at each of 3 visits.
• Biopsy results can identify a cancer of the esophagus you did not know about.

Video capture during the EGD procedure
• No discomfort/risk is expected from the video capture.
• Video images are identified by study identification number. There is the chance that the video images may accidentally identify you; however, that is not planned or expected.

Contacts

Public
Eupraxia Pharmaceuticals Inc.

2067 Cadboro Bay Road 201
Victoria V8R 5G4
CA
Scientific
Eupraxia Pharmaceuticals Inc.

2067 Cadboro Bay Road 201
Victoria V8R 5G4
CA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adults 18 to 75 years of age, inclusive
2. Symptomatic EoE defined as:
a. SDI >= 5 at screening and baseline
b. Confirmed historical diagnosis of EoE with PEC > 15/hpf
3. For women of childbearing potential, a negative pregnancy test (at baseline)

and willing to use a
highly effective method of birth control between baseline and end of study
4. Willing and able to adhere to study-related procedures and visit schedule
5. Willing and able to provide informed consent

Exclusion criteria

1. Any concomitant esophageal disease and relevant GI disease including but not limited to eosinophilic gastritis or enteritis (defined by clinicopathologic features), erosive esophagitis Los Angeles grade C or higher, Barrett*s esophagus, previous esophageal surgery, Celiac disease, inflammatory bowel disease, or any condition or history of illness or laboratory abnormality that in the investigator*s judgment might interfere with study procedures or ability to complete the study,
Note: Participants with occasional gastroesophageal reflux disease (GERD) symptoms without severe (Los Angeles grade C or higher)
endoscopic erosive reflux esophagitis are permitted
2. Presence of oral or esophageal mucosal infection of any type (bacterial, viral, or fungal)
3. Any oropharyngeal or dental condition that prevents normal eating
4. Known severe esophageal motility disorders other than EoE
5. Contraindication to or factors that substantially increase the risk associated with EGD or esophageal biopsy, or narrowing of the esophagus that precludes EGD with a standard 9-10 mm endoscope, stricture requiring dilation within the 8 weeks prior to Screening, or the need for dilation prior to EGD at baseline
A history or presence of any condition for which the use of corticosteroids is contraindicated (e.g., insulin-dependent diabetes mellitus, Cushing*s syndrome, Addison*s disease, cortisol-related endocrinopathy, etc.)
6.Known active or quiescent systemic fungal, bacterial (including tuberculosis), viral (including human immunodeficiency virus [HIV], hepatitis B virus [HBV], or hepatitis C virus [HCV]), or parasitic infections, or ocular herpes simplex. Or any infection requiring intravenous [IV] antibiotics within 4 weeks of baseline, or oral antibiotics within 2 weeks of baseline.
7. Known hypersensitivity, or intolerance to corticosteroids, or to any of the ingredients in the investigational medicinal product, including carboxymethyl cellulose, hyaluronic acid, and polysorbate 80, or to the ingredients in Synacthen (used in the ACTH stimulation test)
8. Use of systemic corticosteroids within 60 days prior to baseline, or swallowed topical corticosteroids within 60 days prior to baseline, or extended use of high-potency dermal topical corticosteroids within 60 days prior to baseline
09. Use of a new inhaled or intranasal corticosteroid within 60 days prior to baseline, or a change in dose of an inhaled or intranasal corticosteroid within 60 days of baseline (a temporary dose change lasting <= 14 days is permitted)

10. Initiation of an elimination diet or elemental diet within 30 days prior to baseline (dietary therapy must remain stable throughout the study)
11. Use of biologic immunomodulators in the 90 days prior to baseline
12. Use of immunosuppressive drugs, or potent cytochrome CYP3A4 inhibitors in the 90 days prior to baseline
13. Initiated, discontinued, or changed dosage regimen of PPIs for any condition such as GERD or allergic rhinitis within 4 weeks prior to baseline. Doses must remain stable throughout the study
14. Morning serum cortisol level <= 5 µg/dL (138 nmol/L) at Screening visit
15. Use of another investigational product within the 30 days prior to baseline, or an investigational biologic within 90 days prior to baseline, or current/planned participation in another interventional trial during this study
16. Previous participation in this study and had received study treatment
17. Female participants who are pregnant, breastfeeding, or planning to become pregnant during the study
18. The following laboratory values:
a. Elevated alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) > 3× upper limit of normal (ULN), bilirubin, alkaline phosphatase (ALP), and/or gamma glutamyl transferase (GGT) > 2× ULN, or creatinine > 1.5× ULN
b. Elevated prothrombin time or international normalized ratio greater than the ULN at screening.
c. Hemoglobin A1c (HbA1c) value of >= 8.0% (64 mmol/mol) at screening.
19. Malignancies or history of malignancy within 5 years of screening, except for adequately treated or completely excised nonmetastatic basal cell carcinoma, squamous cell carcinoma of the skin, or cervical carcinoma in situ
20. History of patient-reported alcohol or drug abuse within 6 months prior to screening
21. Unwillingness to withhold protocol-prohibited medications during the trial
22. Any other reason, including a severe acute or chronic medical or psychiatric condition(s) or laboratory abnormality, that, in the opinion of the investigator, is likely to unfavorably alter participant risk-benefit, confound study results, or make it difficult for the participant to fully comply with study requirements

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2023
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	EP-104IAR
Generic name:	EP-104IAR

Ethics review

Approved WMO Date:	26-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-10-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO

Date:	17-02-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO

Date:	26-03-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO

Date:	31-03-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Approved WMO Date:	14-06-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	14-07-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	10-10-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	12-07-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	CTIS2024-516689-13-00
EudraCT	EUCTR2022-001992-15-NL
ClinicalTrials.gov	NCT05608681
CCMO	NL81772.018.22