# A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Mavorixafor in patients with WHIM Syndrome with Open-Label Extension

Published: 06-04-2020
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This study has been transitioned to CTIS with ID 2024-518461-10-00 check the CTIS register for the current data. • Randomized Placebo-Controlled Period:Primary:- to demonstrate the efficacy of mavorixafor in patients with Warts,...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Immune system disorders congenital |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54582

**Source**
ToetsingOnline

**Brief title**
Mavorixafor (X4P-001) in patients with WHIM Syndrome

### Condition

- Immune system disorders congenital

**Synonym**
immunodeficiency disorder, WHIM Syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** X4 Pharmaceuticals Inc.

**Source(s) of monetary or material Support:** Industry

## Intervention

**Keyword:** Mavorixafor (X4P-001), Phase III, WHIM Syndrome

## Outcome measures

### Primary outcome

•Randomized Placebo-Controlled Period:

Primary endpoints:

- Time above threshold-absolute neutrophil count (TAT-ANC; in hours) of >= 500 cells/µL over a 24-hour period, assessed 4 times throughout the study (every 3 months for 12 months) for the Intent-to-Treat (ITT) Population.

•Open-Label Period

Primary endpoint:

- Safety and tolerability of mavorixafor in patients with WHIM syndrome, as assessed by AEs, clinical laboratory evaluations, vital signs, ECG assessments, and physical and ophthalmologic examinations.

### Secondary outcome

• Randomized Placebo-Controlled Period:

Key Secondary endpoints:

- Time above threshold-absolute lymphocyte count (TAT-ALC) of >= 1000 cells/µL over a 24-hour period assessed 4*times throughout the study (every 3 months for 12 months) in the ITT Population.

- Composite Clinical Efficacy Endpoint for mavorixafor based on total infection

score and total wart change score in the ITT Population.

- Total wart change score for mavorixafor based on central blinded, independent review of 3 target skin regions in the ITT Population.

-Total infection score for mavorixafor based on number and severity of infections adjudicated by a blinded, independent Adjudication Committee (AC) in the ITT Population.

Other Secondary Endpoints:

- Time to Early Release as confirmed by blinded independent AC in the ITT Population.

- TAT-ALC of >= 1000 cells/µL in participants with lymphopenia at baseline.

- Composite endpoint based on total infection score and total wart change score for participants with warts at baseline or participants with non-Ig use.

- Total infection score based on infections adjudicated by a blinded, independent AC for participants with non-Ig use.

- Total wart change score (Clinical Global Impression of Change [CGI-C]) based on blinded central review of 3 target skin regions for participants with warts at baseline.

- Total wart change score (CGI-C) based on local dermatologist review of all regions for participants with warts at baseline.

- Patient Global Impression of Change (PGI-C) from baseline.

- Patient Global Impression of Severity (PGI-S) during treatment.

- Vaccine titer levels at Week 52 in the Randomized Placebo-Controlled Period in all participants vaccinated at Week 13 with tetanus, diphtheria, and

pertussis vaccine (Tdap), including pertussis toxin and tetanus.

- Vaccine titer levels at Week 52 in the Randomized Placebo-Controlled Period for human papillomavirus (HPV) 16 and HPV 18 in all participants receiving vaccinations with HPV 9-valent vaccine, recombinant (Gardasil®9) during the study.

- Change from baseline in wart severity based on local dermatological assessment (all regions) and central dermatological assessment (3 target skin regions) as determined by the Clinical Global Impression of Severity (CGI-S) for participants with warts at baseline and the ITT Population.

- Infection characteristics (eg, type of infection, duration of treatment, severity) by treatment group as adjudicated by an independent AC.

- Infection-free time by treatment group.

- Number of days lost from work/school by treatment group.

- Quality of life by treatment group as measured by the 36-Item Short Form Survey and EQ-5D-5L, Life Quality Index, for all participants.

- Quality of life by treatment group as measured by The Dermatology Life Quality Index.

- Quality of life by treatment group in adolescent participants as measured by the Pediatric Quality of Life Inventory.

- Change from baseline in anogenital (AG) warts, based on dermatologist CGI-C and AG wart severity assessment, in participants with AG evaluation.

- Frequency of events requiring rescue treatment due to infection.

- Incidence, frequency, and duration of hospitalizations due to infections.

- Incidence of newly developed warts.

- Area under the curve for absolute neutrophil count (AUCANC) over 24 hours, calculated using the trapezoidal method.
- Proportion of neutrophil responders, defined as participants with ANC >= 500*cells/µL threshold at least 50% of the time, as well as ANC above threshold for the entire 24-hour period.
- AUCANC over 24 hours, to be assessed by a within-group comparison with the clinically meaningful threshold of >= 500*cells/µL in the mavorixafor treatment group (where the 24-hour threshold area under curve is calculated as 500 × 24).
- AUCALC over 24 hours, calculated using the trapezoidal method.
- Proportion of lymphocyte responders, defined as participants with baseline ALC below the lower limit of normal who achieve on-treatment ALC >= 1000*cells/µL threshold at least 50% of the time, as well as ALC above threshold for the entire 24-hour period.
- Absolute and fold change from baseline for total ALC, absolute monocyte count (AMC), ANC, and white blood cell (WBC) count.
- Absolute and fold change from baseline in absolute numbers of T, B, and natural killer lymphocyte subpopulations.

• Open-Label Period:

Secondary endpoints:

- Proportion of neutrophil responders, defined as participants with ANC >= 500*cells/µL threshold.
- Proportion of lymphocyte responders, defined as participants with baseline

ALC below the lower limit of normal who achieve on-treatment ALC >= 1000*cells/

µL threshold.

- Absolute and fold change from baseline for total ALC, AMC, ANC, and WBC count.

- Vaccine titer levels during the Open-Label Period in all participants

vaccinated with Tdap) during the study, including pertussis toxin and tetanus.

- Vaccine titer levels during the Open-Label Period for HPV 16 and HPV 18 in

all participants receiving vaccinations with HPV 9-valent vaccine, recombinant

(Gardasil®9) during the study.

- Change from baseline in cutaneous warts, based on central review of CGI-C and

CGI-S.

- Change from baseline in cutaneous warts, based on local dermatologist review

of CGI-C and CGI-S.

- Change over time in PGI S and PGI C.

- Total infection score as adjudicated by an independent AC.

# Study description

**Background summary**

WHIM (Warts, Hypogammaglobulinemia, Infections, and Myelokathexis) syndrome is a rare, autosomal dominant, combined primary immunodeficiency syndrome caused by inherited gain of function (GOF) mutations altering the C-X-C chemokine receptor type 4 (CXCR4) receptor carboxyl terminus. The disease is associated with significant morbidity and mortality, primarily due to bacterial, viral and fungal infections, susceptibility to human papilloma virus (HPV) disease and an increased risk of malignancies.

The immune defects in WHIM syndrome arise from the inappropriate retention of otherwise sufficiently functional white blood cells (WBCs) in the bone marrow, including neutrophil retention and impaired interactions among T cells and B cells. These deficiencies underpin the WHIM syndrome symptomatology and can

lead to life-threatening complications.

The precise incidence of WHIM syndrome is unknown but estimated to be less than 1 in a million.

WHIM syndrome typically manifests in early childhood, marked by frequent and severe bacterial infections and the appearance of warts. However, the diagnosis of WHIM syndrome is often delayed: about half of the patients were diagnosed in adulthood.

There are no approved treatments directed at the primary pathophysiology of the syndrome. Current therapeutic options for WHIM patients include parenteral immunoglobulin (Ig) therapy, granulocyte-colony stimulating factor (G-CSF), antibiotic prophylaxis, and hematopoietic stem cell transplantation. In addition, plerixafor, a parenteral CXCR4 inhibitor, is being investigated in patients with WHIM syndrome.
G-CSF and prophylactic Ig therapy are the most commonly prescribed treatments. However, both are nonspecific, difficult to administer, do not address the primary underlying defect, and have limited effectiveness in mitigating hematological defects and preventing infection. Neither treatment addresses the increased susceptibility to HPV-related disease.
The challenges and limitations of the currently available treatment options illustrate that the primary underlying drivers of morbidity in WHIM syndrome remain unaddressed, namely patient quality-of-life (QoL) and vulnerability to life-limiting infection and malignancy.

Mavorixafor is a second-generation, small-molecule, non competitive, allosteric antagonist of CXCR4 that acts by binding to extracellular domains of the receptor, resulting in specific and reversible inhibition of receptor signaling in response to its ligand CXCL12. Mavorixafor is currently in clinical development in patients with oncology (renal cell carcinoma and melanoma) and WHIM syndrome.
The Phase 2 data showed clear evidence of the expected effect of mavorixafor in inducing sustained increase in ANC and ALC at doses >=300 and >=100 mg, respectively.
The preliminary data in 2 patients suggest an overall decrease in non-genital wart burden. There were no changes in Ig levels, and there were too few revaccinations to enable any conclusions.
Mavorixafor appeared to be well tolerated. The most common SOC (system organ class) for TEAEs (treatment-emergent adverse event) was infections and infestations. . There were no SAEs reported, and there was no clinically relevant finding in clinical laboratory values, vital signs, or ECGs.
A dose of 400 mg QD was required to achieve both AUCANC and AUCALC above the levels considered clinically relevant. Given the overall safety profile and the recommendation of the Data Review Committee (DRC), 400 mg QD has been selected as the dose for further investigation in the Phase 3 portion of this study.

**Study objective**

This study has been transitioned to CTIS with ID 2024-518461-10-00 check the CTIS register for the current data.

• Randomized Placebo-Controlled Period:

Primary:
- to demonstrate the efficacy of mavorixafor in patients with Warts, Hypogammaglobulinemia, Infections, and Myelokathexis (WHIM) syndrome as assessed by increasing levels of circulating neutrophils compared with placebo, and relative to a clinically meaningful threshold.

Key Secondary:
- To demonstrate the efficacy of mavorixafor in participants with WHIM syndrome as assessed by increasing levels of circulating lymphocytes compared with placebo and relative to a clinically meaningful threshold.
- To demonstrate the clinical efficacy of mavorixafor in participants with WHIM syndrome as assessed by a composite endpoint of infections and warts.
- To demonstrate the efficacy of mavorixafor in participants with WHIM syndrome as assessed by improvement in warts.
- To demonstrate the efficacy of mavorixafor in participants with WHIM syndrome as assessed by reduction in infections.

Other Secondary:
- To demonstrate the efficacy of mavorixafor in participants with WHIM syndrome including as assessed by participant-reported outcomes.
- To evaluate the safety and tolerability of mavorixafor in participants with WHIM syndrome.
-To evaluate pharmacokinetics (PK) of mavorixafor in participants with WHIM syndrome.

• Open-Label Period:

Primary:
- To evaluate the safety and tolerability of mavorixafor in patients with WHIM syndrome.

Secondary:
- To evaluate the long-term efficacy of mavorixafor in participants with WHIM syndrome.

**Study design**

This is a Phase 3, 2-period study, with an initial 12-month, randomized, double-blind, placebo-controlled period (referred to as the Randomized

Placebo-Controlled Period) followed by an open-label extension (referred to as the Open-Label Period hereafter).

To be eligible for the study, participants must have a diagnosis of WHIM syndrome and a genotype-confirmed mutation of C-X-C chemokine receptor type 4 (CXCR4), be at least 12 years of age, and have a confirmed absolute neutrophil count (ANC) or total white blood cell (WBC) count <= 400 cells/µL at screening, as well as meet all other eligibility criteria.

The Randomized Placebo-Controlled Period comprises a 12 months (52-week) treatment period. Approximately 18 to 28 participants will be randomized 1:1 to mavorixafor or matching placebo and stratified according to the use of immunoglobulin (Ig) therapy, irrespective of the mode of administration (inlcuding subcutaneous or intravebous). The 2 strata are defined as (1) have received any Ig treatment within 5 months prior to screening visit/signing of the informed consent form (ICF), or (2) have not received any Ig treatment within 5 months prior to screening visit/signing of the ICF.

Both the baseline assessments for eligible participants and the administration of the first dose of study drug or placebo will occur during a time period of approximately 28 hours from Day -1 to Day 1. Specifically, the baseline assessments, including an electrocardiogram (ECG) and serial samples for ANC and absolute lymphocyte count (ALC), as well as total WBC count and absolute monocyte count (AMC), will be conducted over 24 hours prior to study drug administration. In the case of systemic infection between screening and baseline, the baseline visit may be postponed for up to 4 weeks or until the ANC has been confirmed to be <= 400 cells/µL. Systemic infections must be resolved prior to first study drug administration. If an infection occurs any time between the screening and the baseline visits, this event will be considered medical history, and the Investigator should record the event via the clinician-reported outcome (ClinRO) mechanism as well as record the event on the Medical History form of the electronic case report form (eCRF).
Participants will be treated with oral mavorixafor 400 mg once daily (QD) except for adolescents weighing <= 50 kg, who will be treated with mavorixafor 200 mg QD.
Participants stratified to the no prior Ig stratum will not be treated with Ig during the duration of the study (including in the Open-Label Period).
Participants in the prior Ig therapy stratum will continue on the same Ig treatment (ie, same dose, mode of administration, and frequency) as administered prior to joining the study. During the study, administration of Ig must not occur within 4 days prior to each visit.
The first dose of study drug will be administered on the morning of Day 1, followed by an ECG at 2 hours postdose (± 30 minutes) and blood draws at 2 hours and 4 hours postdose (each ± 15 minutes) (prior to discharge).
At Weeks 1 and 4 (± 3 days), participants will have a telephone call from the Investigator or designee to evaluate safety and discuss study compliance, followed by scheduled study visits every 13 weeks (ie, Weeks 13, 26, 39, and 52

[± 14 days for all of these visits]). In order to avoid multiple needle sticks, blood sampling for pharmacokinetics (PK), ALC, AMC, ANC, and WBC count may require an indwelling catheter.

Participants will be contacted by phone approximately 72 to 24 hours prior to each scheduled study visit to check if the participants feels that he/she may have an ongoing infection, and to remind the participant not to take his/her study medication at home on the day of the visit, as the study medication will be administered during the visit. In the event of symptoms consistent with infection, the visits may be delayed until the symptoms of infection are cleared.

Rescue use of granulocyte-colony stimulating factor (G-CSF) for up to approximately 2 weeks is permitted after discussion with the Medical Monitor. If an Investigator decides that a participant requires ongoing, regularly scheduled treatment with G-CSF, then the participant must be discontinued from study treatment or be considered for Early Release (Section 5.4.1.1) In the event of rescue treatment with G-CSF or antibiotic therapy any time on or after conducting the baseline visit, visits for ANC measures must be delayed for no less than 14 days and no more than 28 days from the last dose of G-CSF, or no less than 7 days (or 5 half-lives) for the antibiotic in consideration, whichever is longer, and no more than 28 days from the last dose of antibiotics.

Participants will be vaccinated with tetanus, diphtheria, and pertussis (Tdap) and HPV 9-valent vaccine, recombinant (Gardasil®9) according to a predetermined schedule starting at Week 13. Vaccination will be according to respective vaccine schedules for all participants, unless not permitted per standard of care. Revaccination for Gardasil®9 will be per vaccine schedule for participants who have completed a full course of vaccination with Gardasil®9 prior to the study, unless not permitted per standard of care. Antibody specific titers, including pertussis toxin, tetanus, human papillomavirus (HPV) 16, and HPV 18 will be collected in the Randomized Placebo-Controlled Period at baseline, and Weeks 26, 39, 52, and EOS.
In the Randomized Placebo-Controlled Period, information about potential infections will be collected via multiple sources: an electronic participant-reported outcomes (PRO) questionnaire, the ClinRO questionnaire, through information collected by the study team and entered into the Adverse Event of Special Interest - Infections eCRF, and in documents uploaded in the infection adjudication portal. Potential infection events will be evaluated by a blinded, independent Adjudication Committee (AC) as outlined in the AC Charter. The AC will evaluate all potential infection data and determine whether an event is consistent with infection, the characteristics of the infection, the severity of the infection, and whether a given participant may qualify for Early Release from the Randomized Placebo-Controlled Period to the Open-Label Period based on infection severity. The AC will be the final arbiter of infections for the purpose of the efficacy analysis.

The warts Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Change (CGI-C), determined by blinded central review for the target skin regions, will be used for the composite clinical endpoint analysis.
Electronic diaries that contain the PRO questionnaire will be distributed at the baseline visit for the Randomized Placebo-Controlled Period and will include a participant training session. The electronic diaries will be completed daily during both the Randomized and Open-Label Periods.
Participants should continue to receive blinded study drug administration through the Week 52 (ie, the End of Randomized Period [EoRP]) visit.
Participants completing the EoRP have 3 options:
• Roll over to the Open-Label Period: For these participants, the last day of the EoRP visit is the last day of the Randomized Placebo-Controlled Period.
• End participation in the study: These participants and any participants who discontinue study at any time during the Randomized Placebo-Controlled Period will attend an End of Study (EOS) visit at 30 days (± 14 days) post-last dose of study treatment.
• Roll over to long-term follow-up: These participants will have a safety follow-up visit at 30 days (± 14 days) post-last dose of study treatment. The safety follow-up visit will be identical to the EOS in terms of timing and procedures performed.
For participants who discontinue study treatment during the Randomized Placebo-Controll

**Intervention**

Mavorixafor is a second-generation, small-molecule, non-competitive, allosteric antagonist of the CXCR4 receptor.
The mavorixafor dose regimen for both the Randomized Period and the Open-Label Period is 400 mg once daily (QD) for adults. For adolescents (12-17 years of age) weighing >50 kg, the mavorixafor dose will also be 400 mg QD. Adolescents weighing <=50 kg will receive mavorixafor 200 mg QD. Mavorixafor is administered as 100-mg dose strength capsules.
Reference therapy, dosage, and mode of administration: placebo (equivalent number of matching capsules).

**Study burden and risks**

WHIM syndrome is a disease of considerable morbidity and mortality, with no currently available therapy directed against the underlying mechanism of disease. Mavorixafor is an oral agent suitable for QD administration that directly and specifically targets the molecular basis of the disease and is expected to have efficacy at dose levels that will be safe and well tolerated.
For patients participating in this study, the potential clinical benefit of mavorixafor, an orally bioavailable, investigational treatment that directly targets the molecular pathogenesis of WHIM syndrome, outweighs its potential risks when these risks are appropriately monitored and managed.

# Contacts

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**Scientific**
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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)

## Inclusion criteria

1. Be at least 12 years of age.
2. Have signed the current approved Informed Consent Form. Participants under 18 years of age (in the Netherlands and other applicable regions, participants under 16 years of age) will sign an approved informed assent form and must also have a signed parental/legal guardian consent.
3. Have a genotype-confirmed mutation of CXCR4 consistent with WHIM phenotype.
4. Agree to use a highly effective form of contraception, as detailed in Section 5.3.1.
5. Be willing and able to comply with this protocol.
6. Have a confirmed ANC <=400 cells/µL during screening, obtained while participant has no clinical evidence of infection. Local laboratory may be used

if central laboratory is not available.
a. If the ANC is below the lower limit of detection for the laboratory and the total WBC count is <= 400 cells/µL, then the participant is considered eligible for the study.
b. If the ANC is > 400 cells/µL in the context of a recent infection or inflammation prior to screening, it is acceptable to redraw a blood sample and confirm that the ANC meets inclusion criteria (<= 400 cells/µL) once the infection or inflammatory episode is resolved.
c. If the participant experiences an infection or inflammatory episode between screening and baseline that may impact the ANC, or receives G-CSF between screening and baseline, the baseline visit may be postponed for up to 4 weeks until the ANC has been confirmed to be <= 400 cells/µL.

## Exclusion criteria

1. Has known systemic hypersensitivity to the mavorixafor drug substance, its inactive ingredients, or the placebo.
2. Is pregnant or breastfeeding.
3. Has a known history of a positive serology or viral load for HIV or a known history of AIDS.
4. Has, at screening, laboratory tests meeting 1 or more of the following criteria:
* A positive hepatitis C virus antibody with confirmation by hepatitis C virus ribonucleic acid polymerase chain reaction reflex testing.
* A positive hepatitis B surface antigen (HBsAg) or hepatitis B core antibody (HBcAb).
Note: If a participant tests negative for HBsAg but positive for HBcAb, the participant would be considered eligible if the participant tests positive for hepatitis B surface antibody (also referred to as anti-HBsAg) on reflex testing.
5. Has, at screening, safety laboratory tests meeting 1 or more of the following criteria:
* Hemoglobin < 8.0 g/dL
* Platelets < 75,000 cells/µL
* Estimated glomerular filtration rate based on the Modification of Diet in Renal Disease of <= 29 mL/min/1.73 m2 (Stage 4 or 5 chronic kidney disease)
* Serum aspartate aminotransferase > 2.5 × the upper limit of normal (ULN)
* Serum alanine aminotransferase > 2.5 × ULN
* Total bilirubin > 1.5 × ULN (unless due to Gilbert*s syndrome, in which case total bilirubin >= 3.0 × ULN and direct bilirubin > 1.5 × ULN)
6. Had surgery requiring general anesthesia within the 4 weeks prior to Day 1.
7. Received any of the following treatments:
* Plerixafor within 6 months prior to Day 1.
* Chronic or prophylactic use of antibiotics (systemic or inhaled) within 4 weeks prior to Day 1.

* Chronic or prophylactic use of G-CSF or granulocyte macrophage-colony stimulating factor within 2 weeks of Day 1.
* Chronic or prophylactic use of systemic glucocorticoid use (> 5 mg prednisone equivalent per day) within 2 weeks prior to Day 1.
* Any investigational therapy within 5 half-lives or 2 weeks prior to Day 1, whichever is longer. Prior use of any investigational therapies must be discussed with the Medical Monitor.
8. Is currently taking or has, within 2 weeks prior to Day 1, received any medication that is prohibited (see Section 6.4.1), based on potential for drug-drug interactions.
9. Has, at the planned initiation of study drug, a clinically diagnosed active infection (excluding warts) that has the potential to raise the ANC counts.
10. Has had a total splenectomy within 1 year.
11. Has a current diagnosis of myelofibrosis.
12. Has a medical history of hematological malignancies.
13. Has any other medical or personal condition that, in the opinion of the Investigator, may potentially compromise the safety or compliance of the participant or may preclude the participant*s successful completion of the clinical study.
14. Has corrected QT interval using Fridericia*s formula of > 450 ms.
Note: Central results should be used for determination of screening laboratory values when possible. However, local laboratory analysis may be used if central laboratories are not available, or for unscheduled visits, repeated samples, or in place of central laboratory samples that could not be processed or were out of window.
Inclusion criteria for Open-Label Period:
1. Completed the Randomized Placebo-Controlled Period or
2. Granted Early Release from the Randomized Placebo-Controlled Period, as described in Section 5.4.1.1.
3. Blind broken (Section 1.1.1).

# Study design

## Design

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| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

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| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 27-07-2021 |
| Enrollment: | 5 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Mavorixafor |
| Generic name: | N/A |

## Ethics review

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| Approved WMO Date: | 06-04-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 09-09-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 16-12-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-01-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 11-02-2021 |
| Application type: | Amendment |

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|---|---|
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-02-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 10-02-2022 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 29-07-2022 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-05-2023 |
| Application type: | Amendment |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214<br>Postbus 22660<br>1100 DD Amsterdam<br>020 566 7389<br>mecamc@amsterdamumc.nl |
| Approved WMO Date: | 23-05-2023 |
| Application type: | Amendment |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214<br>Postbus 22660<br>1100 DD Amsterdam<br>020 566 7389 |

mecamc@amsterdamumc.nl

# 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 | CTIS2024-518461-10-00 |
| EudraCT | EUCTR2019-001153-10-NL |
| ClinicalTrials.gov | NCT03995108 |
| CCMO | NL70788.018.20 |