# A Phase 2b Randomized, Double-blind, Placebo-controlled, Repeat-dose, Multicenter Trial to Evaluate the Efficacy, Safety and Tolerability of HZN-825 in Subjects with Idiopathic Pulmonary Fibrosis

Published: 19-01-2022
Last updated: 14-09-2024

This study has been transitioned to CTIS with ID 2023-509784-24-00 check the CTIS register for the current data. Core phase: The overall objective of the core phase is to investigate the efficacy, safety and tolerability of 2 dose regimens of HZN-...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53568

**Source**
ToetsingOnline

**Brief title**
HZNP-HZN-825-303

### Condition

- Respiratory disorders NEC

**Synonym**
Idiopathic Pulmonary Fibrosis, Scarred Lungs

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Horizon Therapeutics Ireland DAC
**Source(s) of monetary or material Support:** Horizon Therapeutics Ireland DAC

## Intervention

**Keyword:** HZN-825, Idiopathic Pulmonary Fibrosis (IPF), Lung disease with unknown cause

## Outcome measures

### Primary outcome

Core phase:

Change in FVC % predicted from Baseline to Week 52.

Extension phase:

The primary endpoint is the change from both Baselines in FVC % predicted at

Week 104.

### Secondary outcome

Core phase:

Key secondary efficacy endpoint:

Proportion of subjects with decline in FVC % predicted >=10% from Baseline at

Week 52.

Other secondary efficacy endpoints:

1. Change from Baseline in the 6MWT results to Week 52.

2. Change from Baseline in K-BILD scores to Week 52.

3. Change from Baseline in L-IPF scores to Week 52.

4. Change from Baseline in LCQ scores to Week 52.

5. Time to first hospitalization due to respiratory distress from Baseline up

to Week 52.

6. Time to first onset of the composite endpoint of PFS from Baseline up to

Week 52, where progression includes decline in FVC % predicted >=10% or death.

For exploratory and safety endpoints please refer to the study protocol

Extension phase:

Safety and tolerability endpoints:

• Incidence of TEAEs and the AESI (orthostatic hypotension) in the Extension

Phase

• Concomitant medication use in the Extension Phase

• Change from Trial Baseline in vital signs in the Extension Phase

• Change from Trial Baseline in 12-lead ECG measurements in the Extension Phase

• Change from Trial Baseline in clinical safety laboratory test results in the

Extension Phase

For exploratory please refer to the study protocol

# Study description

**Background summary**

IPF is an advancing and fatal lung disease with significant morbidity and
reported increasing incidence and prevalence. Pirfenidone and nintedanib were

approved by the FDA in 2014 for the treatment of IPF based on positive results in Phase 3 trials, and both of these antifibrotic drugs are conditionally recommended in the 2015 ATS/ERS/JRS/ALAT Clinical Practice Guideline [Raghu et al., 2015]. Although an improvement over previously suggested therapies, their capacity to reduce but not completely arrest progression of lung fibrosis or improve lung function over time presents an opportunity for novel or add-on pharmacologic agents.

Pirfenidone should be taken 3 times daily with food at a target dose that is generally achieved
over 14 days [Lancaster et al., 2017]. Nintedanib recommended dosage includes BID dosing with food. In randomized, double-blind, placebo controlled trials, gastrointestinal adverse reactions occurring in >=10% of treated subjects that may require temporary dosage reductions or discontinuations for pirfenidone and nintedanib included diarrhea, nausea, abdominal pain and vomiting [ESBRIET Full Prescribing Information; OFEV Full Prescribing Information]. While significant advances have been made in the past decade using pharmacological therapy, there remains a substantial unmet clinical need for treatment regimens with improved efficacy, tolerability and dosing convenience for patients with IPF.

HZN-825 is under investigation as a novel therapy for IPF because it selectively antagonizes LPAR1, which has been shown to be associated with skin, pulmonary, cardiac, peritoneal and tubulointerstitial fibrosis and has potential as a new therapeutic for treating fibrotic diseases, including IPF.

This trial is designed to evaluate the efficacy and safety of HZN-825 in subjects with IPF. The trial will be conducted in 2 parts, Part 1 (Core Phase) and Part 2 (Extension Phase). In the Core Phase of the trial, subjects will receive HZN-825 300 mg QD, HZN-825 300 mg BID or placebo during the 52-week Double-blind Treatment Period. Subjects who complete the Double-blind Treatment Period (Week 52) in the Core Phase may be eligible for the Extension Phase and will receive open-label HZN-825 300 mg BID for 52 weeks (up to Week 104). This Extension Phase will allow subjects to have up to 24 months of treatment with HZN-825, as well as limit the duration subjects are exposed to placebo. The trial is designed with the Extension Phase to allow examination of long-term safety and tolerability of HZN-825, assessment of the durability of response and/or improved response in subjects who received HZN-825 in the Core Phase and evaluation of efficacy in subjects who received placebo in the Core Phase.

**Study objective**

This study has been transitioned to CTIS with ID 2023-509784-24-00 check the CTIS register for the current data.

Core phase:
The overall objective of the core phase is to investigate the efficacy, safety

and tolerability of 2 dose regimens of HZN-825, a selective antagonist of lysophosphatidic acid receptor-1 (LPAR1), administered once daily (QD) or twice daily (BID) for 52 weeks in the treatment of subjects with idiopathic pulmonary fibrosis (IPF).

Primary Objective:
The primary objective is to demonstrate the efficacy of 2 dose regimens of HZN-825 versus placebo in subjects with IPF, as determined by a comparison of change in forced vital capacity (FVC) % predicted after 52 weeks of treatment.

Secondary Objectives:
1. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the proportion of subjects with decline in FVC % predicted >=10% from Baseline after 52 weeks of treatment.
2. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the changes from Baseline in the 6 Minute Walk Test (6MWT) after 52 weeks of treatment.
3. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the King's Brief Interstitial Lung Disease Questionnaire (K-BILD) after 52 weeks of treatment.
4. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the Living with IPF (L-IPF) after 52 weeks of treatment.
5. Evaluate the effect of 2 dose regimens HZN-825 versus placebo on the Leicester Cough Questionnaire (LCQ) after 52 weeks of treatment.
6. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the rate of hospitalization due to respiratory distress up to 52 weeks of treatment.
7. Evaluate the effect of 2 dose regimens of HZN-825 versus placebo on the composite endpoint of progression-free survival (PFS), where progression includes decline in FVC % predicted >=10% from Baseline or death over 52 weeks of treatment.
8. Assess safety and tolerability of HZN-825, inclusive of, but not limited to, adverse events (AEs), SAEs and AESI.
9. Evaluate the PK of HZN-825.

For exploratory objectives please refer to the study protocol.

Extension phase:

The overall objective of the Extension Phase is to investigate the long-term efficacy, safety and tolerability of HZN-825, a selective antagonist of LPAR1, administered at a dose of 300 mg BID to subjects with IPF in a 52-week OLE following completion of the Core Phase of the trial. The dose for the Extension Phase may be modified based on the results of the Core Phase.

Two types of Baseline are defined for the Extension Phase:
• OLE Baseline, defined as the latest measurement prior to the first dose of HZN-825 in Extension Phase

• HZN-825 Baseline, defined as the latest measurement prior to the first dose of HZN-825 in either the Core Phase or the Extension Phase. For subjects who received placebo in the Core Phase, OLE Baseline will be the same as HZN-825 Baseline.

Primary objective:
The primary efficacy objective is to assess the efficacy of HZN 825 in subjects with IPF after 52 weeks of open-label treatment.

Safety objective:
The safety objective is to examine the safety and tolerability of 52 weeks of open-label treatment with HZN 825 based on:
• TEAE assessment
• Concomitant medication use
• Vital signs
• 12-lead electrocardiogram (ECG)
• Clinical safety laboratory results

For exploratory objectives please refer to the study protocol.

**Study design**

HZNP-HZN-825-303 (HARBOR) will be conducted at approximately 85 trial sites in North America, Europe, South America, Africa, Asia (including Japan) and Australia. The trial comprises 2 parts. Part 1 (Core Phase) is a randomized, double-blind, placebo-controlled, repeat-dose, multicenter trial to evaluate the efficacy, safety and tolerability of HZN-825 in subjects with IPF. Part 2 (Extension Phase) is an optional, open-label, repeat-dose, multicenter extension of the Core Phase.

Design of the Core Phase of the Trial
This is a randomized, double-blind, placebo-controlled, repeat-dose, multicenter trial to evaluate the efficacy, safety and tolerability of HZN-825 in subjects with IPF. Subjects will be screened within 8 weeks prior to the Baseline (Day 1) Visit. Approximately 135 subjects who meet the trial eligibility criteria will be randomly assigned in a 1:1:1 ratio on Day 1 to receive HZN-825 300 mg QD, HZN-825 300 mg BID or placebo for 52 weeks using the following 2 stratification factors:
1. Concomitant use of approved IPF therapy (i.e., nintedanib or pirfenidone): yes or no
2. FVC % predicted at Baseline: >=70% or <70%

The Core Phase will include up to an 8-week Screening Period and a 52-week Double-blind Treatment Period. Subjects will take their first dose of trial drug at the clinic on Day 1 (Week 0) and will participate in trial visits at Week 4 and every 6 weeks thereafter until Week 52. Subjects who complete the 52-week Double blind Treatment Period may be eligible to enroll into the

Extension Phase of the trial. If the subject does not enroll into the Extension Phase, a Safety Follow-up Visit will occur 4 weeks after the last dose of trial drug.

If a subject prematurely discontinues trial drug, he/she will be asked to remain in the trial, participating in the scheduled trial visits through Week 52. If a subject prematurely discontinues trial drug and does not wish to continue in the trial, he/she will be asked to return for a clinic visit and undergo the Week 52 assessments.

Design of the Extension Phase of the Trial
The Extension Phase of the trial is an optional, open-label, repeat-dose, multicenter extension of the Core Phase. Subjects who complete the Double-blind Treatment Period (Week 52) in the Core Phase of the trial may be eligible to enter this 52 week Extension Phase. Subjects entering the Extension Phase will complete the Week 52 Visit, which will be considered Day 1 of the Extension Phase, and will receive their first dose of open-label HZN-825 in the Extension Phase at the clinic and return to the clinic for trial visits at Weeks 56, 62 and 68, then every 12 weeks through Week 104. The Week 52 Visit activities will serve as Baseline for the Extension Phase. Subjects will return to the clinic for a Safety Follow-up Visit 4 weeks after the last dose of HZN 825.

If a subject prematurely discontinues HZN-825, he/she will be asked to remain in the trial, participating in the scheduled trial visits through Week 104. If a subject prematurely discontinues HZN-825 and does not wish to continue in the trial, he/she will be asked to return for a clinic visit and undergo the Week 104 assessments.

**Intervention**

Core phase: Subjects will take 2 tablets of trial drug orally in the morning and evening with a meal.
• HZN-825 300 mg QD regimen: 2 HZN-825 tablets in the morning and 2 placebo tablets in the evening
• HZN-825 300 mg BID regimen: 2 HZN-825 tablets in the morning and 2 HZN-825 tablets in the evening
• Placebo regimen: 2 placebo tablets in the morning and 2 placebo tablets in the evening

Extension Phase: The dose regimen for all subjects will be HZN-825 300 mg BID. Subjects will take 2 HZN 825 150 mg tablets orally in the morning and evening with a meal. The dose for the Extension Phase may be modified based on the results of the Core Phase.

**Study burden and risks**

HZN-825 is a new therapeutic agent under development for treating fibrotic diseases, including SSc. The anti-inflammatory and anti-fibrotic properties of LPAR1 antagonism have been demonstrated in both animal models and in a Phase 2a clinical trial. Positive changes in mRSS, HAQ-DI and LPAR1 pathway genes were detected in the completed Phase 2a trial in diffuse cutaneous SSc. Results of trials to date support the safety and potential efficacy of 300 mg BID for up to 24 weeks of treatment. The exposure, PK and safety profiles of HZN-825 were similar across the completed trials.

Based on the cumulative safety data available to date on HZN-825, orthostatic hypotension, drug-drug interactions, embryo-fetal toxicity and liver toxicity are considered as important potential risks. No severe AEs or SAEs were reported in healthy subjects in Phase 1 trials. TEAEs of orthostatic hypotension, postural dizziness, flatulence and abdominal pain were slightly more frequent in HZN-825-treated than in placebo-treated subjects. Orthostatic hypotension was mainly observed in healthy subjects and tended to be less marked in subjects with diffuse cutaneous SSc treated with HZN-825. The potential safety risk of HZN-825 due to drug-drug interactions is considered low as medications that may have potential interactions with HZN-825 are restricted in this protocol (Section 9.4.9).

Participants with IPF receiving HZN-825 may benefit from the LPAR1 antagonism by slowing the decline of lung function due to progressive fibrotic disease. Subjects in the trial will also benefit from receiving trial-related medical examinations, imaging and laboratory tests at no cost.

AESIs are considered monitorable. Taking into account mitigation measures to minimize risk to subjects in this trial, the potential risks identified in association with HZN 825 treatment and the trial as a whole are justified by the anticipated benefits that may be afforded to patients with IPF.

Additional information regarding the benefit and risks of HZN-825 are located in the current Investigator*s Brochure Section 6.2 and Section 1.2.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Core phase:
1. Written informed consent.
2. Male or female >=18 years of age at Screening.
3. Current diagnosis of IPF, as defined by American Thoracic Society (ATS)/European Respiratory Society (ERS)/Japanese Respiratory Society (JRS)/Latin American Thoracic Society (ALAT) guidelines [Raghu et al., 2022] and determined by central review; the date of initial diagnosis of IPF should be <=7 years prior to Screening.
4. No recent changes or planned changes to the dose or regimen for IPF therapy, defined as:
• Receiving a stable dose of IPF-approved therapy (i.e., nintedanib or pirfenidone) for a minimum of 3 months prior to Day 1 with no plans to change the background regimen during trial participation, or
• Not currently receiving background IPF-approved therapy at Screening (either naïve to IPF-approved therapy or previously discontinued any IPF-approved therapy at least 4 weeks prior to Day 1 or drug-specific, 5 half-lives elimination period if longer than 4 weeks), and with no current plans to restart treatment during trial participation
• Subjects receiving any additional agent for IPF therapy must be on a stable regimen for at least 3 months prior to Day 1 with no current plans to change the treatment regimen during trial participation. Any previously discontinued therapy used to treat IPF must have been discontinued at least 4 weeks prior to Day 1 or 5 half-lives for that specific therapy must have elapsed, whichever is longer, with no plans to restart the therapy during trial participation.

5. Lung HRCT historically performed within 6 months prior to the Screening Visit and according to the minimum requirements for IPF diagnosis by central review based on subject's HRCT. If an evaluable HRCT is not available within 6 months prior to Screening, an HRCT will be performed at Screening to determine eligibility, according to the same requirements as the historical HRCT. The HRCT must demonstrate a usual interstitial pneumonia or probable usual interstitial pneumonia pattern based on central review vendor interpretation. Histopathology in combination with HRCT results supportive of an IPF or IPF likely diagnosis according to Raghu et al., 2022 can be submitted to support subject eligibility.
6. HRCT shows >=10% to <50% parenchymal fibrosis (reticulation) and the extent of fibrotic changes is greater than the extent of emphysema on the most recent HRCT scan (central reviewer determined).
7. Meets all of the following criteria during the Screening Period, as determined by central review:
a. FVC >=45% predicted of normal
b. forced expiratory volume in 1 second (FEV1)/FVC >=0.7
c. DLCO corrected for hemoglobin is >=25% and <=90% predicted of normal
8. Estimated minimum life expectancy of >=30 months for non-IPF-related disease, in the opinion of the Investigator.
9. Vaccinations are up to date, according to the Investigator*s discretion, given age, comorbidities and local availability prior to trial drug dosing.
10. Willing and able to comply with the prescribed treatment protocol and evaluations for the duration of the trial.

Extension phase:
1. Written informed consent.
2. Completed the Double-blind Treatment Period (Week 52) of the Core Phase of the trial; subjects prematurely discontinued from trial drug in the Core Phase of the trial for reasons other than safety or tolerability may be included at the discretion of the Investigator after completing scheduled visits, including Week 52 assessments.
3. Willing and able to comply with the prescribed treatment protocol and evaluations for the duration of the Extension Phase of the trial.

## Exclusion criteria

Core phase:
1. Any of the following cardiovascular diseases:
a. uncontrolled, severe hypertension (>=160/100 mmHg), within 6 months of Screening
b. myocardial infarction within 6 months of Screening
c. unstable cardiac angina within 6 months of Screening
2. Interstitial lung disease (ILD) associated with known primary diseases (e.g., sarcoidosis, amyloidosis and coronavirus disease 2019 [COVID-19]),

connective tissue disorders (e.g., rheumatoid arthritis, systemic lupus erythematosus, Sjogren*s, dermatomyositis, scleroderma), exposures (e.g., radiation, silica, asbestos and coal dust) or drugs (e.g., amiodarone).
3. Known active bacterial, viral, fungal, mycobacterial or other infection, including tuberculosis or atypical mycobacterial disease (fungal infections of nail beds are allowed). The subject must be 3 months beyond any acute infection with COVID-19 if there has been a prior infection.
4. Clinically significant pulmonary hypertension requiring chronic medical therapy.
5. Use of any of the following therapies within 4 weeks prior to Screening, during the Screening Period or planned during the trial: prednisone at steady dose >10 mg/day or equivalent or cyclosporine. Prednisone <=10 mg/day (or equivalent dosing of glucocorticoids) is allowed. Change in regimen or dosage of any immunosuppressant during the Screening Period through the end of trial participation will require consultation with and approval by the trial Medical Monitor. See Section 9.4.9 for full details. Avoiding the use of listed prohibited treatments must not be considered detrimental and must be indicated by the treating physician. Subjects must not be withdrawn from any standard-of-care treatment that is considered necessary for the clinical management of the subject in order to fulfill the trial eligibility requirements.
6. Use of rifampin within 2 weeks prior to Day 1 or planned during the trial.
7. Malignant condition in the past 5 years (except successfully treated basal/squamous cell carcinoma of the skin or cervical cancer in situ).
8. Women of childbearing potential (WOCBP) or male subjects not agreeing to use highly effective method(s) of birth control throughout the trial and for 4 weeks after last dose of trial drug. Females must refrain from egg/ova donation for 4 weeks after the last dose of trial drug and males must refrain from sperm donation for 3 months after the last dose of trial drug. Women are considered of childbearing potential if they are not postmenopausal and not surgically sterile (documented bilateral salpingectomy, bilateral oophorectomy or hysterectomy). A postmenopausal state is 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. Fertile male subjects must use a condom throughout the trial and for 4 weeks after the last dose of trial drug. A man is considered fertile after puberty unless permanently sterile by bilateral orchidectomy.
9. Pregnant or lactating women and women who plan to become pregnant or breast feed during the trial and within 4 weeks after the last dose of trial drug.
10. Current drug or alcohol abuse or history of either within the previous 2 years, in the opinion of the Investigator or as reported by the subject.
11. Previous enrollment in this trial or participation in a prior HZN-825 or SAR100842 clinical trial.
12. Known history of positive test for human immunodeficiency virus (HIV). HIV

testing is optional based on Investigator assessment, institutional practices or local guidelines to rule out suspected HIV or potential for a positive HIV result. Subject consent is required prior to HIV testing.
13. Active hepatitis (any of the following at Screening):
Hepatitis B:
• positive hepatitis B surface antigen
• positive for anti-hepatitis B core antibody (anti HBcAb) and a positive test for hepatitis B surface antibody (HBsAb) and presence of hepatitis B virus DNA
• positive for HBcAb and a negative test for HBsAb and presence of hepatitis B virus DNA
Hepatitis C:
• positive anti hepatitis C virus (anti HCV) and positive HCV RNA.
14. Current alcoholic liver disease, primary biliary cirrhosis or primary sclerosing cholangitis.
15. Previous organ transplant (including allogeneic and autologous marrow transplant).
16. International normalized ratio >2, prolonged prothrombin time >1.5 × the upper limit of normal (ULN) or partial thromboplastin time >1.5 × ULN at Screening.
17. Alanine aminotransferase or aspartate aminotransferase >2.0 × ULN.
18. Estimated glomerular filtration rate <30 mL/min/1.73 m2 at Screening.
19. Total bilirubin >1.5 × ULN. Subjects with documented diagnosis of Gilbert*s syndrome may be enrolled if their total bilirubin is <=3.0 mg/dL.
20. Moderate (Child-Pugh B) to severe (Child-Pugh C) hepatic impairment according to the Child-Pugh scoring system.
21. Any confirmed Grade 3 or higher laboratory abnormality.
22. Any laboratory abnormality at Screening that, in the opinion of the Investigator, would preclude the subject*s participation in the trial.
23. Exposure to an experimental drug or experimental vaccine within either 30 days, 5 half-lives of the test agent, or twice the duration of the biological effect of the test agent, whichever is the longest, prior to Day 1.
24. Any other condition that, in the opinion of the Investigator, would preclude enrollment in the trial.

Extension phase:
1. Anticipated use of another investigational agent for any condition during the course of the trial.
2. New diagnosis of malignant condition after enrolling in Trial HZNP-HZN-825-303 (except successfully treated basal/squamous cell carcinoma of the skin or cervical cancer in situ).
3. Estimated minimum life expectancy <=18 months, in the opinion of the Investigator.
4. WOCBP or male subjects not agreeing to use highly effective method(s) of birth control throughout the Extension Phase and for 4 weeks after last dose of HZN-825. Females must refrain from egg/ova donation for 4 weeks after the last dose of trial drug and males must refrain from sperm donation for 3 months after the last dose of trial drug. Women are considered of childbearing

potential if they are not postmenopausal and not surgically sterile (documented bilateral salpingectomy, bilateral oophorectomy, or hysterectomy). A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high 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. A man is considered fertile after puberty unless permanently sterile by bilateral orchidectomy.
5. Pregnant or lactating women.
6. Any other new development of the disease/condition/significant laboratory test abnormality during the course of the Core Phase of the trial, in the opinion of the Investigator, that would potentially put the subject at unacceptable risk.
7. In the opinion of the Investigator, unlikely to comply with the trial protocol or has a concomitant disease or condition that could interfere with the conduct of the trial.

# Study design

## Design

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| Study phase: | 2 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 29-09-2022 |
| Enrollment: | 4 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | HZN-825 |
| Generic name: | HZN-825 |

## Ethics review

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|---|---|
| Approved WMO Date: | 19-01-2022 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 11-04-2022 |
| Application type: | First submission |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 01-10-2022 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 05-10-2022 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 18-11-2022 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 28-11-2022 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 28-01-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

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|---|---|
| Approved WMO Date: | 06-03-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 02-07-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 19-07-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 04-08-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |
| Approved WMO Date: | 16-08-2023 |
| Application type: | Amendment |
| Review commission: | METC Brabant (Tilburg) |

# 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 |
|---|---|
| Other | NCT05032066 |

| Register | ID |
| --- | --- |
| EU-CTR | CTIS2023-509784-24-00 |
| EudraCT | EUCTR2021-001253-32-NL |
| CCMO | NL79812.028.22 |