A Randomized, Multicenter, Phase 3 Study of Zanidatamab in Combination with Chemotherapy with or without Tislelizumab in Subjects with HER2-positive Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma (GEA)

Published: 22-09-2021
Last updated: 10-01-2025

This study has been transitioned to CTIS with ID 2023-510319-20-00 check the CTIS register for the current data. Primary objective:- To compare the efficacy of zanidatamab in combination with chemotherapy or in combination with chemotherapy and…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON54341

Source
ToetsingOnline

Brief title
HERIZON-GEA-01

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Unresectable Locally Advanced or Metastatic Gastroesophageal Adenocarcinoma / Stomach

or esophageal cancer that cannot be operated surgery and/or has metastasized.

Research involving
Human

Sponsors and support

Primary sponsor: Jazz Pharmaceuticals Ireland Limited
Source(s) of monetary or material Support: Zymeworks Inc.

Intervention

Keyword: Gastroesophageal Adenocarcinoma, Phase 3, Tislelizumab (BGB-A317), Zanidatamab (ZW25)

Outcome measures

Primary outcome

- Progression-free survival (PFS) by the Response Evaluation Criteria in Solid

Tumors version 1.1 (RECIST 1.1), assessed by blinded independent central review

(BICR)

- Overall survival (OS)

Secondary outcome

- Confirmed objective response rate (ORR) by RECIST 1.1, assessed by BICR

- Duration of response (DOR) by RECIST 1.1, assessed by BICR

- PFS by RECIST 1.1, per investigator assessment

- Confirmed ORR by RECIST 1.1, per investigator assessment

- DOR by RECIST 1.1, per investigator assessment

- Overall survival (OS)

- PFS by RECIST 1.1, by BICR

- Frequency, type, severity, seriousness, and relatedness of adverse events

(AEs)

- Frequency and severity of clinical laboratory abnormalities

- Change from baseline in health economics and outcomes research /

patient-reported outcomes (HEOR/PRO) parameters

- Serum concentration and PK parameters for zanidatamab

- Serum concentration for tislelizumab

- Frequency, duration, and time of onset of anti-zanidatamab antibodies and

neutralizing antibodies, if applicable

- Frequency, duration, and time of onset of anti-tislelizumab antibodies and

neutralizing antibodies, if applicable

Study description

Background summary

Zanidatamab is being investigated as a new therapy for HER2 positive GEA. Zanidatamab sticks to HER2 and can kill HER2-positive cancer cells. It is comparable with the current standard therapy (trastuzumab) that also sticks to HER2. Zanidatamab sticks to two different places on HER2, while trastuzumab sticks to one place on HER2, so the way they work may be different.

Tislelizumab is also being investigated in this study. Tislelizumab can stick to a protein present on the surface of immune cells. This protein prevents that the body*s immune cells recognize or kill specific cancer cells. Tislelizumab can block this protein and restore the cancer-kiling function of the immune cells.

Study objective

This study has been transitioned to CTIS with ID 2023-510319-20-00 check the CTIS register for the current data.

Primary objective:
- To compare the efficacy of zanidatamab in combination with chemotherapy or in combination with chemotherapy and tislelizumab to the efficacy of trastuzumab in combination with chemotherapy in subjects with unresectable locally advanced, recurrent or metastatic HER2 positive GEA

Secondary objectives:

- To further compare the efficacy of zanidatamab in combination with chemotherapy or chemotherapy and tislelizumab to chemotherapy with trastuzumab
- To assess contribution of components of tislelizumab in combination with zanidatamab and chemotherapy
- To evaluate the safety and tolerability of zanidatamab in combination with chemotherapy or chemotherapy and tislelizumab
- To evaluate the effect of zanidatamab in combination with chemotherapy or chemotherapy and tislelizumab on health-related quality of life (HRQoL)
- To evaluate the pharmacokinetics (PK) of zanidatamab in combination with chemotherapy or chemotherapy and tislelizumab
- To evaluate the PK of tislelizumab in combination with chemotherapy and zanidatamab
- To evaluate the immunogenicity of zanidatamab in combination with chemotherapy or chemotherapy and tislelizumab
- To evaluate the immunogenicity of tislelizumab in combination with chemotherapy and zanidatamab

Exploratory objectives:
- To evaluate ongoing anti-tumor effects of zanidatamab with or without tislelizumab and with chemotherapy after start of new therapy
- To evaluate the utility of potential biomarkers that may be associated with efficacy, resistance, and/or safety of zanidatamab in combination with chemotherapy, with or without tislelizumab
- To evaluate the PK of trastuzumab in combination with chemotherapy
- To evaluate the immunogenicity of trastuzumab in combination with chemotherapy

Study design

This is a randomized, 3-arm, open-label, active-comparator, global phase 3 study to investigate the efficacy and safety of zanidatamab in combination with standard of care chemotherapy with or without tislelizumab in subjects with advanced or metastatic GEA, including gastric, gastroesophageal junction (GEJ), and esophageal adenocarcinomas. Subjects must not have received prior systemic anticancer therapy in the advanced/metastatic setting, and must not have received prior human epidermal growth factor receptor 2 (HER2)- or programmed cell death-1 / programmed death-ligand 1 (PD-1/PD-L1)-targeted therapy in any setting.
New or archival tumor tissue (most recent biopsy) for screening is required from all subjects for assessment of HER2 gene amplification and HER2 protein expression. Enrollment will be based on central laboratory assessment of HER2 status. Assessment of microsatellite instability (MSI) status and PD-L1 expression will not be required for enrollment but will be performed retrospectively.
Upon enrollment, subjects will be stratified according to geographic region (Asia, European Union [EU]/North America, Rest of World), HER2 status per central assessment (3+ immunohistochemistry [IHC] staining, 2+ IHC staining

with in situ hybridization [ISH]-positivity), and Eastern Cooperative Oncology Group performance status (ECOG PS; 0, 1), and randomized 1:1:1 to one of 3 treatment arms:
• Arm A: Trastuzumab (Herceptin®) plus physician*s choice of capecitabine plus oxaliplatin (CAPOX) or 5-fluorouracil (5-FU) plus cisplatin (FP)
• Arm B: Zanidatamab plus physician*s choice of CAPOX or FP
• Arm C: Zanidatamab and tislelizumab plus physician*s choice of CAPOX or FP
Investigator decision regarding the chemotherapy regimen (CAPOX or FP) must be determined prior to randomization, and subjects should continue on the selected regimen throughout the duration of chemotherapy. Disease response will be evaluated using computed tomography (CT) or magnetic resonance imaging (MRI) scans. Assessment scans will be performed every 6 weeks (Q6W) for the first 54 weeks and every 9 weeks (Q9W) thereafter.

Intervention

Patients will be randomised in 3 different groups in a 1:1:1 ratio.

Group A. The people in this group will get trastuzumab with chemotherapy (standard of care). Trastuzumab will be given every 3 weeks as a single infusion into a vein.

Group B. The people in this group will get zanidatamab with chemotherapy. Zanidatamab will be given every 3 weeks via an infusion. Before administration of zanidatamab, pre-medication to reduce your risk of having an allergic reaction to the study drug will be provided. Patients will also be prescribed a medication to prevent diarrhea which needs to be taken with the first dose of study drug and a few days after that.

Group C. The people in this group will get zanidatamab with tislelizumab and chemotherapy. Zanidatamab will be given every 3 weeks via an infusion. Tislelizumab will be administered every 3 weeks after the administration of zanidatamab. Before administration of zanidatamab, pre-medication to reduce your risk of having an allergic reaction to the study drug will be provided. Patients will also be prescribed a medication to prevent diarrhea which needs to be taken with the first dose of study drug and a few days after that.

Study burden and risks

The use of zanidatamab with or without combination with tislelizumab is known to cause side effects. Also the standard therapy trastuzumab has known side effects. The subjects will also receive chemotherapy with a known risk profile.

Most common side effects for zanidatamab (seen in more than 20% of people who have taken zanidatamab):
- Diarrhea, including severe diarrhea that might cause dehydration

- Nausea
- Vomiting
- Fatigue
- Infusion-related reactions (Fever, Chills, Low blood pressure, Fast heart rate, Weakness, Headache, Rash, Scratchy throat, Nausea and vomiting, Difficulty breathing or swallowing, Hives or skin rash and Swelling)

In addition:
Because zanidatamab works in a similar way as other HER2-targeted drugs that may cause heart problems, there may or may not occur heart problems during the course of the treatment. Patients will be informed to contact their physician directly with symptoms of heart problems, such as chest pain, shortness of breath, swelling of the ankles, and/or tiredness.
In rare cases, allergic reactions can be life-threatening, and require immediate medical attention and stopping treatment. These symptoms can be wheezing, pain and tightness in the chest, swelling, hives, skin rash, feeling weak and fainting.
A type of white blood cell called neutrophils helps to fight infection. Zanidatamab may lower your white blood cells (neutropenia).

Most common side effects for tislelizumab (occurring in at least 10% of people):
- Nausea
- Diarrhea
- Constipation
- Vomiting
- Tiredness
- Fever
- Abnormal liver function measured by liver tests
- Rash
- Itching
- Anemia
- Decreased appetite
- Cough
- Underactive thyroid gland (possible feeling cold, weight gain, heart failure, and/or constipation)

In addition:
Tislelizumab, and other drugs similar to tislelizumab, are thought to act against cancer by activating the immune system to attack cancer. However, in some patients there can be side effects related to an overactive immune system, which can cause damage to your organs or other tissues of your body. In most patients, these adverse reactions are temporary and can be treated by stopping tislelizumab and giving other medications that block the immune system.

Most common side effects for trastuzumab (occurring in at least 10% of people) include:
- Low white blood cell counts

- Diarrhea
- Feeling tired
- Low red blood cell counts
- Swelling of the mouth lining
- Weight loss
- Upper respiratory tract infections
- Fever
- Low platelet counts
- Swelling of the mucous membranes
- Swelling of the nose and throat
- Change in taste

In addition:
Trastuzumab can cause serious side effects:
- Heart Problems: These include heart problems - such as congestive heart failure or reduced heart function - with or without symptoms. The risk for and seriousness of these heart problems were highest in people who received both trastuzumab and a certain type of chemotherapy (anthracycline; this type of drug is not being used in this study). In a study of adjuvant (early) breast cancer, one patient died of significantly weakened heart muscle.
- Infusion-related reactions. The injection of study drug into the vein can cause a reaction, similar to an allergy, during or after the infusion. Symptoms of an infusion related reaction include: fever and chills, nausea, vomiting, pain (in some cases at tumor sites), headache, dizziness, shortness of breath. These signs usually happen within 24 hours after receiving trastuzumab.
- Severe Lung problems: Signs include: severe shortness of breath, fluid in or around the lungs, weakening of the valve between the heart and the lungs, not enough oxygen in the body, swelling of the lungs, scarring of the lungs, low white blood cell counts. Low white blood cell counts can be life threatening. Low white blood cell counts were seen more often in patients receiving trastuzumab plus chemotherapy than in patients receiving chemotherapy alone.

Also, the study procedures may be accompanied with risks and discomforts. In addition to the study drug, the procedures and the combination of these may lead to risks that are currently not known.

The sponsor feels that the side effects and the burden associated with participation are in proportion considering the positive effects that participation in the study might have on the patient's disease progression.

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

1. Prior treatment with a HER2-targeted agent, with the exception of subjects who received HER2-targeted
treatment for breast cancer > 5 years prior to initial diagnosis of GEA.
2. Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2 or any other antibody or drug specifically
targeting T-cell co-stimulation or checkpoint pathways.

Exclusion criteria

PRIOR TREATMENT WITH A HER2-TARGETED AGENT, WITH THE EXCEPTION OF SUBJECTS WHO
RECEIVED HER2-TARGETED TREATMENT FOR BREAST CANCER > 5*YEARS PRIOR TO INITIAL DIAGNOSIS OF GEA.

PRIOR TREATMENT WITH AN ANTI-PD-1, ANTI-PD-L1, ANTI-PD-L2 OR ANY OTHER ANTIBODY OR DRUG SPECIFICALLY TARGETING T-CELL CO-STIMULATION OR CHECKPOINT PATHWAYS.

PRIOR TREATMENT WITH SYSTEMIC ANTINEOPLASTIC THERAPY OR INTRAPERITONEAL CHEMOTHERAPY FOR UNRESECTABLE LOCALLY ADVANCED, RECURRENT OR METASTATIC GEA.
SUBJECTS WHO HAVE RECEIVED TREATMENT WITH ADJUVANT OR NEOADJUVANT CHEMOTHERAPY
OR CHEMORADIOTHERAPY MUST NOT HAVE CANCER RECURRENCE OR PROGRESSION WITHIN 6*MONTHS OF COMPLETING THAT THERAPY. SUBJECTS WHO HAVE RECEIVED PRIOR PALLIATIVE LOCAL THERAPY (E.G., RADIATION THERAPY) ARE ELIGIBLE.

RECEIVED RADIATION THERAPY WITHIN 14 DAYS PRIOR TO RANDOMIZATION.

TOTAL LIFETIME ANTHRACYCLINE LOAD EXCEEDING 360 MG/M2 DOXORUBICIN OR EQUIVALENT.

ANY CONDITION THAT REQUIRES SYSTEMIC TREATMENT WITH EITHER CORTICOSTEROIDS (> 10 MG DAILY OF PREDNISONE OR EQUIVALENT) OR OTHER IMMUNOSUPPRESSIVE MEDICATION
<= 14 DAYS PRIOR TO RANDOMIZATION (<=*4 WEEKS FOR SUBJECTS WITH CENTRAL NERVOUS
SYSTEM [CNS] METASTASES; SEE EXCLUSION CRITERION #11). NOTE: SUBJECTS WHO ARE CURRENTLY OR HAVE PREVIOUSLY BEEN ON ANY OF THE FOLLOWING STEROID REGIMENS ARE
NOT EXCLUDED:

Adrenal replacement steroid (dose <= 10 mg daily of prednisone or equivalent).

Topical, ocular, intra-articular, intranasal, or inhaled corticosteroid with minimal systemic absorption.

Short course (<= 7 days) of corticosteroid prescribed prophylactically (e.g., for contrast dye allergy) or for the treatment of a non-autoimmune condition (e.g., delayed-type hypersensitivity reaction caused by contact allergen).

HISTORY OF HYPERSENSITIVITY OR CONTRAINDICATIONS TO ANY ACTIVE SUBSTANCE/ACTIVE INGREDIENT OF ANY STUDY MEDICATION, INCLUDING CHEMOTHERAPY COMPONENTS (CISPLATIN, OXALIPLATIN, 5-FLUOROURACIL, OR CAPECITABINE), MURINE PROTEINS (TRASTUZUMAB), MONOCLONAL ANTIBODIES, RECOMBINANT PROTEINS, AND/OR ANY OF THE EXCIPIENTS LISTED IN THE INGREDIENTS OF ANY DRUG FORMULATION.

IN FRANCE AND ITALY, ASSIGNMENT TO STANDARD-OF-CARE CHEMOTHERAPY SHOULD ACCOUNT
FOR THE FOLLOWING CONTRAINDICATIONS:

Subjects with known hearing impairment must not be assigned to a cisplatin-containing regimen.

Subjects with baseline CrCl <*60 mL/min must not be assigned to a

cisplatin-containing regimen.

Subjects with hypokalemia, hypomagnesemia, or hypocalcemia of any grade at the time of enrollment must not be assigned to an oxaliplatin-containing regimen.

KNOWN PARTIAL OR COMPLETE DIHYDROPYRIMIDINE DEHYDROGENASE (DPD) DEFICIENCY OR
USE OF ANY MEDICATIONS KNOWN TO INHIBIT DPD (INCLUDING BRIVUDINE, SORIVUDINE AND ANALOGS) WITHIN 4 WEEKS PRIOR TO RANDOMIZATION. IN FRANCE, TESTING OF PLASMA URACIL CONCENTRATION IS MANDATORY AT BASELINE; IN ITALY, TESTING FOR DPD DEFICIENCY IS MANDATORY AT BASELINE.

MAJOR SURGERY WITHIN 28 DAYS PRIOR TO RANDOMIZATION.

THE FOLLOWING DISEASE-RELATED RISK FACTORS:

Clinically significant bleeding (Common Toxicity Criteria for Adverse Events (NCI CTCAE, 2017)*>=*Grade*3) from the gastrointestinal (GI) tract within 4 weeks prior to randomization.

Clinically significant bowel obstruction (CTCAE*>=*Grade*3).

Accumulation of pleural, ascitic, or pericardial fluid requiring drainage within 2 weeks prior to randomization.

UNTREATED CNS METASTASES, SYMPTOMATIC CNS METASTASES, OR RADIATION TREATMENT FOR CNS METASTASES WITHIN 4 WEEKS PRIOR TO RANDOMIZATION. STABLE, TREATED BRAIN
METASTASES ARE ALLOWED (DEFINED AS SUBJECTS WHO ARE COMPLETELY OFF STEROIDS AND
ANTICONVULSANTS AND ARE NEUROLOGICALLY STABLE WITH NO EVIDENCE OF RADIOGRAPHIC
PROGRESSION FOR AT LEAST 4 WEEKS PRIOR TO RANDOMIZATION).

KNOWN HISTORY OF OR ONGOING LEPTOMENINGEAL DISEASE (LMD). SUBJECTS WILL BE ELIGIBLE IF LMD HAS BEEN REPORTED RADIOGRAPHICALLY BUT IS NOT SUSPECTED CLINICALLY BY THE INVESTIGATOR AND THE SUBJECT DOES NOT HAVE NEUROLOGICAL SYMPTOMS OF LMD.

POORLY CONTROLLED SEIZURES. (FOR SUBJECTS WITH A HISTORY OF SEIZURES, THE LEVEL OF SEIZURE CONTROL WILL BE DETERMINED BY THE INVESTIGATOR BASED ON LOCAL OR REGIONAL GUIDELINES.)

KNOWN ADDITIONAL MALIGNANCY THAT IS NOT CONSIDERED CURED OR THAT HAS REQUIRED
TREATMENT WITHIN THE PAST 3*YEARS. EXCEPTIONS INCLUDE CANCERS WITH A VERY LOW LIKELIHOOD OF RECURRENCE (I.E., TREATMENTS ADMINISTERED HAVE A REPORTED >*95%

CURE RATE OR <*5% RECURRENCE RATE), INCLUDING EARLY-STAGE CANCERS (CARCINOMA IN
SITU OR STAGE I) TREATED WITH CURATIVE INTENT, BASAL CELL CARCINOMA OF THE SKIN, SQUAMOUS CELL CARCINOMA OF THE SKIN THAT HAS UNDERGONE CURATIVE THERAPY,
AND IN SITU CERVICAL CANCER.

SEVERE CHRONIC OR ACTIVE INFECTIONS REQUIRING SYSTEMIC ANTIBACTERIAL, ANTIFUNGAL OR ANTIVIRAL THERAPY (EXCEPTION: ANTIVIRALS FOR HEPATITIS B ARE ALLOWED IF SUBJECTS ARE TREATED FOR >2 WEEKS PRIOR TO RANDOMIZATION) [SEE EXCLUSION CRITERION #17A].

ACUTE OR CHRONIC UNCONTROLLED RENAL DISEASE, PANCREATITIS, OR LIVER DISEASE (WITH EXCEPTION OF SUBJECTS WITH GILBERT*S SYNDROME, ASYMPTOMATIC GALL STONES, LIVER METASTASES, OR STABLE CHRONIC LIVER DISEASE PER INVESTIGATOR ASSESSMENT).

KNOWN ACTIVE HEPATITIS, INCLUDING THE FOLLOWING:

Acute or chronic hepatitis B (Exception: subjects who are hepatitis B surface antigen [HBsAg] positive are eligible if they have hepatitis B virus (HBV) DNA less than 500 IU/mL or 2,500 copies/mL). Note:*Subjects with detectable HBsAg or detectable HBV DNA should be managed per institutional or local guidelines. Subjects beginning antiviral agents at Screening should be treated for >*2 weeks prior to randomization.

Infection with hepatitis C (Exception [i] subjects who have no history of curative viral treatment and are documented to be viral load negative are eligible; [ii] subjects who have completed curative viral therapy >= 12 weeks prior to randomization, and viral load is negative are eligible).

ANY HISTORY OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION.

KNOWN SARS-COV-2 INFECTION; SUBJECTS WITH PRIOR INFECTION THAT HAS RESOLVED PER LOCAL INSTITUTIONS* REQUIREMENTS AND SCREENING GUIDANCE ARE ELIGIBLE.

CLINICALLY SIGNIFICANT CARDIAC DISEASE, SUCH AS VENTRICULAR ARRHYTHMIA REQUIRING THERAPY, UNCONTROLLED HYPERTENSION OR ANY HISTORY OF SYMPTOMATIC CONGESTIVE HEART FAILURE (CHF). SUBJECTS WITH KNOWN MYOCARDIAL INFARCTION OR UNSTABLE ANGINA WITHIN 6 MONTHS PRIOR TO RANDOMIZATION ARE ALSO EXCLUDED. PREVIOUS ANTICANCER THERAPYRELATED CHF MUST HAVE BEEN <= GRADE 1 AT THE TIME OF
OCCURRENCE AND MUST HAVE COMPLETELY RESOLVED.

SYMPTOMATIC PULMONARY EMBOLISM <= 28 DAYS PRIOR TO RANDOMIZATION.

ANY HISTORY OF CEREBROVASCULAR ACCIDENT <= 6 MONTHS PRIOR TO RANDOMIZATION.

QTC FRIDERICIA (QTCF) > 470 MS. NOTE: FOR SUBJECTS WITH LONGER QTCF ON INITIAL ELECTROCARDIOGRAM (ECG), FOLLOW-UP ECG MAY BE PERFORMED IN TRIPLICATE AND THE MEAN OF THE 3 VALUES WILL BE USED TO DETERMINE ELIGIBILITY.

ONGOING, CLINICALLY SIGNIFICANT TOXICITY (GRADE 2 OR HIGHER) ASSOCIATED WITH PRIOR CANCER THERAPIES, WITH THE EXCEPTION OF ALOPECIA.

ONGOING GRADE 2 OR GREATER PERIPHERAL NEUROPATHY.

ONGOING GRADE 2 OR GREATER DIARRHEA.

PRIOR ALLOGENEIC STEM CELL TRANSPLANTATION OR ORGAN TRANSPLANTATION.

HISTORY OF INTERSTITIAL LUNG DISEASE OR NON-INFECTIOUS PNEUMONITIS, OR WITH SEVERE DYSPNEA AT REST OR REQUIRING SUPPLEMENTARY OXYGEN THERAPY.

ACTIVE AUTOIMMUNE DISEASES OR HISTORY OF AUTOIMMUNE DISEASES THAT MAY RELAPSE WITH THE FOLLOWING EXCEPTIONS:

Controlled Type 1 diabetes.

Hypothyroidism (provided it is managed with hormone replacement therapy only).

Controlled celiac disease.

Skin diseases not requiring systemic treatment (e.g., vitiligo, psoriasis, alopecia).

Any other disease that is not expected to recur in the absence of external triggering factors.

ADMINISTERED A LIVE VACCINE <= 4 WEEKS PRIOR TO RANDOMIZATION.

FEMALES WHO ARE BREA

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-07-2022
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BGB-A317
Generic name:	Tislelizumab
Product type:	Medicine
Brand name:	Herceptin
Generic name:	Trastuzumab
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	ZW25
Generic name:	Zanidatamab

Ethics review

Approved WMO Date:	22-09-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	11-02-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-03-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-06-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-09-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-04-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	08-07-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-08-2024
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
EU-CTR	CTIS2023-510319-20-00
EudraCT	EUCTR2021-000296-36-NL
CCMO	NL77656.028.21