A PHASE 3 TRIAL OF FIANLIMAB (REGN3767, ANTI-LAG-3) + CEMIPLIMAB VERSUS PEMBROLIZUMAB IN PATIENTS WITH PREVIOUSLY UNTREATED UNRESECTABLE LOCALLY ADVANCED OR METASTATIC MELANOMA

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This study has been transitioned to CTIS with ID 2023-505772-30-00 check the CTIS register for the current data. From protocol amendment 3 27JUn2022, Clinical Study Protocol Synopsis, page 1Primary Objective• To demonstrate superiority of fianlimab...

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON53805

Source
ToetsingOnline

Brief title
Regeneron R3767-ONC-2011 (0456/0468)

Condition

- Skin neoplasms malignant and unspecified

Synonym
advanced skin cancer; metastatic melanoma

Research involving

Human

Sponsors and support

Primary sponsor: Regeneron Pharmaceuticals Inc.
Source(s) of monetary or material Support: Regeneron Pharmaceuticals Inc.

Intervention

Keyword: advanced melanoma, metastatic melanoma, skin cancer, untreated melanoma

Outcome measures

Primary outcome

From protocol amendment 1 16Feb2022, Clinical Study Protocol Synopsis, page 25

The primary endpoint is:

• PFS (progression-free survival) (per Response Evaluation Criteria in Solid

Tumors (RECIST) 1.1 based on blinded independent central review [BICR]).

Secondary outcome

From protocol amendment 1 16Feb2022, Clinical Study Protocol Synopsis, page

25-26

Efficacy:

The key secondary endpoints are:

• OS (overall survival).

• ORR (objective response rate), defined as the proportion of patients who

achieve a best overall response of CR (complete response) or PR (partial

response) (per RECIST 1.1, based on BICR).

Efficacy:

The additional secondary endpoints for efficacy are:

• DCR (disease control rate), defined as the proportion of patients who achieve a best overall response of CR or PR or stable disease (SD) (per RECIST 1.1 based on BICR; SD assessed at least 6 months after first dose).

• DoR (duration of response), defined as the time from initial response (CR or PR per RECIST 1.1) to first occurrence of PD (progressive disease) (per RECIST 1.1 via BICR), or death due to any cause, whichever occurs first.

• PFS, ORR, DCR, and DoR based on investigator assessment according to RECIST 1.1 and iRECIST (immune RECIST).

Safety:

The safety secondary endpoints are:

• The incidence of adverse events (AEs), treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), adverse events of special interest (AESIs), and immune-related adverse events (irAEs).

• Occurrence of interruption and discontinuation of study drug(s) due to AEs (TEAEs, AESIs, and irAE).

• Incidence of deaths.

• Incidence of laboratory abnormalities.

PK:

The PK secondary endpoints are:

• Concentrations of cemiplimab and fianlimab in serum.

Immunogenicity:

The immunogenicity secondary endpoints are:

• Incidence and titer of anti-drug antibodies (ADA) and incidence of

neutralizing antibodies (NAb) to fianlimab and cemiplimab over time.

Patient Reported Outcomes:

The global health status secondary endpoints are:

• Patient-reported outcomes, as measured by EORTC QLQ-C30, EQ-5D-5L,

FACT-melanoma (melanoma subscale only), PGIS, and PGIC.

• Change from baseline in Physical functioning at Week 25 per EORTC QLQ-C30

• Change from baseline in Role functioning at Week 25 per EORTC QLQ-C30

• Change from baseline in GHS/QoL at Week 25 per EORTC QLQ-C30

• Change from baseline in Physical functioning during the study per EORTC

QLQ-C30

• Change from baseline in Role functioning during the study per EORTC QLQ-C30

• Change from baseline in GHS/QoL during the study per EORTC QLQ-C30

Study description

Background summary

From protocol amendment 1 16Feb2022, section 1. Introduction

1.2. Phase 3 Study, R3767-ONC-2011
Despite the recent advances in the treatment of unresectable or metastatic melanoma, a significant portion of patients do not respond to or progress within 12 months of treatment with current immune checkpoint inhibitors or combination blockade. In addition, combination blockade of CTLA-4 + PD-1 carries significant potential for toxicity, demonstrating the need for

additional therapies with comparable efficacy but with a more favorable safety profile. In view of the results of study CheckMate-067, there is a rationale for exploring new combination of
immune-checkpoint inhibitors that build upon the activity of anti-PD-1 agents but with a more favorable toxicity profile than the ipilimumab-nivolumab combination.

Preliminary studies with fianlimab + cemiplimab in anti-PD-(L)1 naïve advanced melanoma patients suggest that this combination in the first line treatment may prove more efficacious than anti-PD-1 treatment alone, and with a better tolerability than CTLA-4 + PD-1 inhibition.

Additional background information on the study drug and development program can be found in the Investigator*s Brochure for fianlimab.

Thus, this phase 3 study of the combination of fianlimab and cemiplimab versus pembrolizumab in patients with previously untreated unresectable locally advanced or metastatic melanoma is planned.

Study objective

This study has been transitioned to CTIS with ID 2023-505772-30-00 check the CTIS register for the current data.

From protocol amendment 3 27JUn2022, Clinical Study Protocol Synopsis, page 1

Primary Objective
• To demonstrate superiority of fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg+ cemiplimab compared to pembrolizumab, as measured by progression-free survival (PFS).

Secondary Objectives
• To demonstrate superiority of fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg + cemiplimab compared to pembrolizumab, as measured by overall survival (OS).
• To demonstrate superiority in ORR of fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg + cemiplimab compared to pembrolizumab.
• To characterize the ORR, PFS, and OS with fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg + cemiplimab compared to cemiplimab to inform the contribution of each components.
• To assess immunogenicity of fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg and cemiplimab.
• To assess impact of fianlimab 1600 mg + cemiplimab and/or fianlimab 400 mg + cemiplimab on physical functioning and role functioning and global health status/quality of life, as compared to pembrolizumab in adults.
• To characterize safety and tolerability of treatment in patients 12 to <18 years of age.

• To characterize ORR, PFS, and OS with treatment in patients 12 to <18 years of age.
• To assess the safety and tolerability of fianlimab + cemiplimab compared to pembrolizumab and to cemiplimab.
• To characterize pharmacokinetics (PK) of treatment using sparse PK sampling in patients aged >=12 years.

Study design

From protocol amendment 3 27Jun2022, Clinical Study Protocol Synopsis, page 2

This is a phase 3 study in patients aged >=12 years with unrespectable locally advanced or metastatic melanoma who have not received a previous systemic treatment for advanced disease.
For adult and adolescent patients there are 4 main arms to the study, which will be conducted in a randomized, double-blind fashion:
• Arm A: fianlimab (1600 mg every 3 weeks [Q3W], intravenously, [IV]) + cemiplimab (350 mg Q3W IV)
• Arm A1: fianlimab (400 mg every 3 weeks [Q3W], intravenously, [IV]) + cemiplimab (350 mg Q3W IV)
• Arm B: pembrolizumab (200 mg Q3W IV) + saline/dextrose placebo (placebo)
• Arm C: cemiplimab (350 mg Q3W IV) + saline/dextrose placebo (placebo)

The study will enroll a total of approximately 1,590 patients.

• Approcimately1230 patients will be randomized in the first portion of the study. The first 180 randomized patients will be used for a futility analysis conducted by sponsor. These 180 patients include approximately 40 patients enrolled in a 2:1:1 randomization ratio (20 for Arm A and 10 each for Arms B and C) under Protocol Amendment #1, and approximately 140 patients (40 each for Arms A, A1, and B and 20 for Arm C) in 2:2:2:1 randomization ratio under Protocol Amendment 03. The next up to 1,050 patients will be randomized in a 2:2:2:1 randomization ratio (300 patients each for Arms A, A1, and B and 150 patients for Arm C). These patients (the PFS population) will be used for primary analysis of primary endpoint of PFS between Arms A and/or A1 versus Arm B. The PFS population will also be used for final analysis of a secondary endpoint of ORR and for the assessment of contribution of components to the combination of cemiplimab and fianlimab in Arms A and/or A1 versus Arm C.
• The next additional approximately 360 patients will be randomized in a 1:1:1 randomization ratio (120 patients) each for Arms A, A1, and B . These patients together with the PFS population will result in a total of 1410 patients 420 each for Arms A, A1, and B and 150 for arm C) for OS for analysis. The analysis of PFS discussed above will not be conducted until the study is fully enrolled with these additional patients

All patients enrolled in the study will be stratified based on clinical prognostic indicators: by their baseline lactate dehydrogenase (LDH) level

(normal vs elevated), M stage (stage III vs M1a-b vs M1c vs M1d, according to eighth Edition of American Joint Committee on Cancer melanoma classification), and previous exposure to anti-Programmed Death 1 (PD 1)/Programmed Death Ligand 1 (PD-L1) therapy in the adjuvant or neo-adjuvant setting (yes vs no).

Blinding
For all parameters, the study will be blinded, except for an unblinded pharmacist at each site.

Unblinding
Unblinding will occur upon request to Regeneron Medical Monitor by the Investigator after confirmation of disease progression by the Blinded Independent Central Review (BICR).
Emergency unblinding by the Investigator will be permitted in case of a true medical emergency
Patients who have confirmed disease progression will receive standard of care treatment as per their local guidance and investigator*s decision.

Intervention

From protocol amendment 3 27Jun2022, Clinical Study Protocol Synopsis, page 6-7

Dose/Route/Schedule: The combination of cemiplimab plus fianlimab, the combination of pembrolizumab plus placebo and the combination of cemiplimab plus placebo will be prepared by an unblinded pharmacist at the investigative site and will be administered in a blinded fashion for all patients.
All infusions for adults and adolescents will be administered as a 30 minute (±10 minutes) IV infusion in an outpatient setting, every 3 weeks.

Cemiplimab
Cemiplimab 350 mg Q3W IV is the approved regimen (LIBTAYO®, cemiplimab) for treatment of cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma (BCC), and non-small cell lung carcinoma (NSCLC).
Cemiplimab will be supplied as a liquid in sterile, single-use vials.
Instructions on dose preparation are provided in the pharmacy manual.

Fianlimab and Cemiplimab (for combination / co-infusion administration)
Based on efficacy and safety data from an ongoing phase 1 study, R3767-ONC-1613, the fianlimab 1600 mg Q3W IV dose with cemiplimab 350 mg Q3W IV was recommended to advance to phase 3. The efficacy of fianlimab 400 mg Q3W IV with cemiplimab 350 mg Q3W IV has not been studied but is being added as it is in line with the expectation to consider lower doses in oncology setting and also consistent with the doses used for other anti-LAG-3 antibodies that are being utilized in phase 2 and 3 clinical trials in melanoma and in other solid tumors.
Fianlimab 1600 mg and400 mg Q3W IV will be supplied as a liquid in sterile, single-use vials. Instructions on dose preparation are provided in the pharmacy

manual.
Fianlimab and cemiplimab will be administered simultaneously as a mixed co-infusion.

Pembrolizumab
Pembrolizumab 200 mg Q3W IV is an approved dose for the treatment of advanced and metastatic melanoma.
For adolescent patients randomized to Arm B, pembrolizumab will be dosed based on body weight at 2.0 mg/kg Q3W IV (max. 200 mg).
Pembrolizumab will be prepared for co-infusion (with saline placebo) at the investigative sites as a liquid in sterile. Instructions on dose preparation are provided in the pharmacy manual.

Safety: The first 6 adolescent patients (12 to <18 years old) will be allocated to treatment Arm A and included in a safety run-in to confirm the safety and tolerability of the 1600 mg dose of fianlimab (Q3W) in combination with cemiplimab (350mg Q3W) in adolescent patients with melanoma. Subsequent adolescent patients will be randomized to all study arms.
The dose limiting toxicity (DLT) evaluation period for pediatrics is 28 days with the intent to monitor the safety and tolerability of the first 2 doses of study drug(s). The dose will be considered acceptable for randomization of additional adolescent patients if there is no more than 1 DLT in the first 6 evaluable patients. In the event of >1 DLT in the first 6 evaluable patients, see Section 6.1.2.

Study burden and risks

From protocol amendment 1 16Feb2022, section 3 Hypothesis and Rationale:
3.3. Risk-Benefit
A patient being screened for R3767-ONC-2011 who has documented or suspected ongoing SARS CoV-2 infection should not be enrolled in the study.
A patient being screened for R3767-ONC-2011 who had either documented or suspected SARS CoV-2 may be enrolled per the investigator*s medical judgment if the patient has:
• Recovered from COVID-19 (all COVID-19-related symptoms and major clinical findings which can potentially affect the safety of the patient have resolved) and:
* It is recommended at least one COVID-19 PCR test be conducted to confirm that the patient is negative for SARS-CoV-2.
* If COVID-19 PCR testing is not feasible, it is advised that at least three months have transpired since the initial diagnosis.

3.3.1. Risk Benefit for Fianlimab + Cemiplimab
The primary objective of the Study 2011 is to demonstrate the superiority for the proposed combination of fianlimab+cemiplimab (Arm A) compared to the pembrolizumab, an approved therapy (Arm B) in patients with previously untreated unresectable locally advanced or metastatic melanoma.

Cutaneous melanoma is one of the most aggressive forms of skin cancer and its incidence in both males and females has continued to rise over the past 40 years (Section 1.1).

Antibodies to the inhibitory receptor lymphocyte-activation gene 3 (LAG-3), such as fianlimab, represent an appealing potential treatment strategy to invigorate the immune response to cancer, especially in combination with antibodies that block PD-1, such as cemiplimab. See Section 3.2.1.5. for rationale of selection of cemiplimab.

Early clinical data indicate that melanoma patients who received previous anti-PD-1 therapy but progressed can respond to concurrent blockade of LAG-3 and PD 1 (Ascierto, 2017). Ex vivo analyses, in studies in patients with metastatic melanoma, provide impetus to study the hypothesis that therapeutic blockade of both LAG-3 and PD-1 may lead to enhanced T-cell function and clinically meaningful responses compared to PD-1 monotherapy (Section 1.1.4).

The ongoing FIH study, R3767-ONC-1613, included a cohort of patients with advanced melanoma who were naïve to PD-(L)1 inhibition therapy. In these patients, the response rate to combination cemiplimab and fianlimab therapy is approximately 66% (22/33 patients; (Hamid, 2021), comparing favorably to landmark PD-1 inhibition response rates of approximately 26-45% (with caveats of small patient numbers in study 1613, follow-up time differences, investigator assessed vs central review, etc) (Topalian, 2014) (Robert, 2015a) (Robert, 2015b), (Carlino, 2018) (Larkin, 2019).

The safety of the fianlimab (1600mg) in combination with cemiplimab (350mg) has been shown in FIH study 1613 and the current version of the Investigator*s Brochure. The overall safety profile of the fianlimab + cemiplimab combination is generally similar to that observed with cemiplimab monotherapy and other anti-PD-1 antibodies. Adrenal insufficiency was reported at a higher rate in patients treated with the finalimab+cemiplimab combination than those treated with cemiplimab monotherapy, these events were mostly low grade and all manageable with corticosteroids. The rate of adrenal insufficiency that has been observed is similar to that reported with anti-CTLA-4 + anti-PD-1 treatment (8.9% fianlimab + cemiplimab vs 8% ipilimumab + nivolumab, vs 0.5% cemiplimab monotherapy) (see fianlimab IBv5, nivolumab USPI, and cemiplimab IBv7 respectively), and within the same range as reported for relatlimab + nivolumab 4.2%-13% [reported rates vary depending on the study: 4.2% (a randomized phase 3 study of the combination relatlimab + nivolumab vs nivolumab, (Lipson, 2021)) and 13% (a single arm neo-adjuvant/adjuvant study of the combination, (Amaria, 2021))]. Other endocrinopathies and immune-related adverse events have been observed to occur at similar rates compared to anti-PD-1 monotherapy. As summarized in the current Investigator Brochure, the important identified risks of the fianlimab combination with cemiplimab include IRR and irAEs, and these risks were well managed with the risk minimization strategy implemented in the study.

While no adolescent patients were enrolled in phase 1 study R3767-ONC-1613, the safety profile in the adolescent patient population is anticipated to be comparable to that seen in adults (Section 6.1.1). In addition, to further minimize the potential for unexpected safety risks of fianlimab in combination

with cemiplimab in adolescent patients, a 6-patient safety lead-in is included in this phase 3 study (Section 6.1, Adolescents). Subsequent adolescent patients will be randomized to Arms A, B, or C. Despite the small numbers of adolescent patients affected with melanoma, these patients are often diagnosed with melanoma which display a genomic profile similar to that seen in adults, indicating that therapies for adult patients could also be efficacious in the adolescent patient population. Including adolescent patients in the phase 3 study will provide clinical evidence on the safety, PK and efficacy to assess the benefit-risk of the combination of fianlimab + cemiplimab in adolescents with melanoma.
Thus, taking into account the risk minimization measures outlined in this phase 3 protocol to minimize important risks to patients, the potential for therapeutic benefit and medical need for new combination therapy, the risk-benefit profile is anticipated to be positive for coadministration of fianlimab, anti-LAG-3 antibody, with cemiplimab, anti-PD-1, in the phase 3 study, in the population of patients with previously untreated, unresectable locally advanced or metastatic melanoma.

3.3.2. Risk Benefit for Cemiplimab Monotherapy
Cemiplimab monotherapy serves as a comparator (Arm C) in this study to assess the contribution of cemiplimab to the proposed combination. See Section 3.2.1.5. for rationale of selection of cemiplimab.
LIBTAYO® has been approved by Health Authorities for the treatment of patients with locally advanced/metastatic CSCC, BCC and NSCLC in TPS PD-L1 >=50%. The similar weight-based Q2W dose (3 mg/kg) has shown preliminary clinical evidence of monotherapy cemiplimab on efficacy with similar safety profile in patients with melanoma enrolled in Study R2810-ONC-1606.
In this study, cemiplimab will be administered at the approved dose (350 mg Q3W) in patients with previously untreated, unresectable locally advanced or metastatic melanoma, and the risk-benefit is considered to be favorable given the risk minimization outlined in the study protocol to manage the important risks known for cemiplimab.

3.3.3. Risk Benefit for the Active Comparator, Pembrolizumab
Pembrolizumab serves as the active comparator (Arm B) for this study. Pembrolizumab is approved, using the dose regimen, in the US and EU for the treatment of adult patients with unresectable or metastatic melanoma (Keytruda [Summary of Product Characteristics], 2021) (Pembrolizumab [Package Insert], 2021). See Section 3.2.1.5 for information on the rationale for inclusion of pembrolizumab.

Contacts

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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. Age >=12 years on the date of providing informed consent. Note: Patients who are <18 years will be included in the territories, where accepted, per local laws and regulations. In Canada, Italy, Turkey, Poland and South Africa, patients <18 will not be enrolled
2. Patients with histologically confirmed unresectable Stage III and Stage IV (metastatic) melanoma (AJCC, 8th revised edition) who have not received prior systemic therapy for advanced unresectable disease.
a. Patients who received adjuvant and/or neoadjuvant systemic therapies are eligible if they did not have evidence of progression or recurrence of disease and/or discontinued due to occurrence of unmanageable irAEs >= Grade 3 (with the exclusion of endocrinopathies which are fully controlled by hormone replacement) while on such therapies. Also, patients must have had a treatment-free and disease-free interval of >6 months.
b. Patients with acral and mucosal melanomas are eligible. Accrual will be limited to 10% of the total population.

3. Measurable disease per RECIST v1.1
a. Previously irradiated lesions can only be counted as target lesions if they have been demonstrated to progress and no other target lesion is available
b. Cutaneous lesions should be evaluated as non-target lesions
4. Performance status:
a) For adult patients: Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1
b) For pediatric patients: Karnofsky performance status >=70 (patients >=16 years) or Lansky performance status >=70 (patients <16 years)
5. Anticipated life expectancy of at least 3 months.

Please note other protocol-defined Inclusion criteria apply

Exclusion criteria

Medical conditions:
1. Uveal melanoma
2. Ongoing or recent (within 2 years) evidence of an autoimmune disease that required systemic treatment with immunosuppressive agents. The following are non-exclusionary: vitiligo, childhood asthma that has resolved, residual hypothyroidism that requires only hormone replacement, psoriasis not requiring systemic treatment.
3. Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B (HBV) or hepatitis C virus (HCV) infection; or diagnosis of immunodeficiency that is related to, or results in chronic infection.
4. Unknown BRAF V600 mutation status. Patients with BRAF-mutated melanoma who present with symptoms of rapidly progressive disease and are considered by Investigator*s assessment as likely to benefit from upfront treatment with BRAF/MEK-inhibitors should not be enrolled in the study.
Prior/concomitant therapy:
5. Systemic immune suppression:
a. Use of immunosuppressive doses of corticosteroids (<=10mg of prednisone per day or equivalent) within 14 days of the first dose of study medication. Physiologic replacement doses are allowed up to and including 10mg of prednisone/day or equivalent. Inhaled or topical steroids are permitted, provided if they are not for treatment of an autoimmune disorder.
b. Other clinically relevant forms of systemic immune suppression.
6. Treatment with other anti-cancer therapy including immuno- therapy, chemotherapy, radiotherapy, major surgery or biological therapy within 3 weeks prior to the first dose of trial treatment. Adjuvant hormonotherapy used for breast cancer or other hormone-sensitive cancers in long term remission is allowed.
Other comorbidities:
7. History or current evidence of significant (CTCAE Grade >=2) local or systemic infection (e. g., cellulitis, pneumonia, septicemia) requiring

systemic antibiotic treatment within 2 weeks prior to the first dose of trial medication.
8. Active or untreated brain metastases or spinal cord compression. Patients with leptomeningeal disease are excluded. Patients with known brain metastases are eligible if they:
a. received radiotherapy or another appropriate standard therapy for the brain metastases,
b. have neurologically returned to baseline (except for residual signs and symptoms related to the CNS treatment) for at least 14 days prior to enrollment.
c. did not require immunosuppressive doses of corticosteroids therapy (>10mg of prednisone per day or equivalent) in the 14 days prior to enrollment.
Note: Patients with asymptomatic single untreated brain metastasis < 10 mm in size are eligible

Other protocol-defined Exclusion criteria apply

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-10-2022
Enrollment:	7
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	Keytruda
Generic name:	pembrolizumab
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Libtayo
Generic name:	cemiplimab
Product type:	Medicine
Brand name:	not available
Generic name:	Fianlimab

Ethics review

Approved WMO Date:	21-06-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	29-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	CTIS2023-505772-30-00
EudraCT	EUCTR2021-004453-23-NL
ClinicalTrials.gov	NCT05352672
CCMO	NL81602.100.22