A Phase 3, INterVentional, Double-Blind, Placebo Controlled Study to Assess the Safety and Efficacy of DCC-2618 In Patients with AdvanCed Gastrointestinal Stromal TUmorS who have Received Treatment with Prior Anticancer Therapies

Published: 08-01-2018
Last updated: 10-01-2025

Primary Objectives:• To assess the efficacy (progression free survival [PFS]) of DCC 2618 by independent radiologic review in patients with advanced gastrointestinal stromal tumors (GIST) who have received prior therapiesKey Secondary Objectives:•…

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal infections
Study type	Interventional

Summary

ID

NL-OMON50251

Source
ToetsingOnline

Brief title
INVICTUS

Condition

- Gastrointestinal infections

Synonym
gastrointestinal sromal tumors

Research involving
Human

Sponsors and support

Primary sponsor: Deciphera Pharmaceuticals, LLC
Source(s) of monetary or material Support: Deciphera Pharmaceuticals;LLC

Intervention

Keyword: DCC 2618, GIST

Outcome measures

Primary outcome

Primary Endpoint:

PFS based on independent radiologic review using modified RECIST (; Appendix 17.1). Modified RECIST criteria includes:

• No lymph nodes chosen as target lesions; enlarged lymph nodes followed as non target lesions;

• No bone lesions chosen as target lesions;

• Positron emission tomography not acceptable for radiological evaluation;

• A progressively growing new tumor nodule within a pre-existing tumor mass must meet the following criteria to be considered as unequivocal evidence of progression according to the modification of RECIST Version 1.1: (a) the lesion is at least 2 cm in size and definitively a new active GIST lesion (eg, enhancing with contrast or other criteria to rule out artefact); or (b) the lesion has to be expanding on at least 2 sequential imaging studies.

Secondary outcome

Key Secondary Efficacy Endpoint:

• Objective response rate (confirmed CR + confirmed PR)

Secondary Efficacy Endpoints:

• TTP based on independent radiologic review

• OS

• Time to best response

• PFS based on Investigator assessment

• Quality of life as determined by changes from baseline in European

Organisation for Research and Treatment of Cancer Quality of Life Questionnaire

for Cancer 30 item and EuroQol 5-Dimension 5-Level

• Disease control rate (complete response [CR] + partial response [PR] + stable

disease) at 12 weeks

Study description

Background summary

DCC-2618, an inhibitor of KIT and PDGFRA kinases, is being developed for the treatment
of patients with GIST, in addition to other advanced malignancies driven by proto-oncogene
tyrosine-protein kinases. In addition to KIT and PDGFRA, the drug inhibits CSF1R (FMS),
VEGFR2, and TIE2, which are less frequently documented to initiate tumor development.
Gastrointestinal stromal tumors represent the most common form of sarcoma, a relatively
rare subset of cancers arising from mesenchymal cells in the body. Adult GIST occurs
with an incidence rate of ~3,000-6,000 new cases per year in the US, generally presents around age 50-70, and occurs in men and women at similar rates. Surgery is the
primary treatment for localized GIST and can be curative, though local and/or distant
recurrence occurs in more than half of patients. For metastatic or unresectable GIST, which is present in about half of patients at diagnosis, radiotherapy and traditional

chemotherapy are not effective. The era of targeted cancer therapies has ushered in
several new effective treatments for metastatic and recurrent GIST, though CRs are rarely
achieved. Resistance to therapy occurs in a large majority of patients within a few
months to years depending on treatment, similar to that observed in other cancers
successfully treated with targeted therapies.

DCC-2618 is a novel, oral inhibitor of KIT kinase and PDGFRA kinases, developed by
Deciphera Pharmaceuticals, LLC (hereafter referred to as the *Sponsor*), using its
proprietary kinase switch control inhibitor technology platform. DCC-2618 comprehensively
and potently inhibits a broad range of primary and secondary mutants of KIT and PDGFRA
kinases, including KIT primary mutations in exons 9 and 11 and secondary resistance
mutations in exon 13 and 14 of the KIT ATP binding/switch pocket region and primary or
secondary mutations in exons 17 and 18 of the activation loop conformation-controlling
switch region. DCC-2618 also inhibits the PDGFRA primary exon 18 mutation D842V in the
conformation-controlling switch region and exon 12 mutations in the auxiliary inhibitory
switch. DCC-2618 exhibits this broad profile of mutant KIT/PDGFRA inhibition by binding
as an advanced Type II kinase inhibitor that penetrates the embedded KIT/PDGFRA switch
pockets.

DCC-2618, and its active metabolite, DP-5439, were evaluated in vitro in recombinant
kinase assays and in cellular assays with GIST cell lines from treatment-resistant patients,
AML and mastocytosis cell lines, or cell lines transfected with KIT or PDGFRA mutants.
These studies provided a comprehensive profile of inhibition versus clinically relevant KIT
and PDGFRA mutations that cause either de facto refractoriness to existing therapies or
resistance to existing therapies. Results from evaluation in cancer cell lines guided further
evaluation of DCC-2618 in refractory/resistant in vivo xenograft models.

A variety of cancer model systems were employed to evaluate the pharmacology of DCC-2618 in vivo, including the evaluation of efficacy in human tumor xenografts in nude
mice and pharmacokinetic (PK)/pharmacodynamic (PD) studies in tumor-bearing mice to
evaluate exposures required for durable mutant KIT inhibition in vivo.

In vivo, DCC-2618 exhibited potent anti-tumor effects in mutant KIT GIST models. Additionally, DCC-2618 showed potent inhibition of KIT phosphorylation in GIST models.

DCC-2618 was selected for clinical development based on the efficacy and tolerability
observed in these model systems.

Study objective

Primary Objectives:
• To assess the efficacy (progression free survival [PFS]) of DCC 2618 by independent radiologic review in patients with advanced gastrointestinal stromal tumors (GIST) who have received prior therapies
Key Secondary Objectives:
• To assess objective response rate by independent radiologic review
Secondary Objectives:
• To assess other parameters of efficacy, including but not limited to time to progression (TTP) and overall survival (OS)
• To assess the PD/PK relationship of DCC-2618
• To assess the robustness of efficacy using a sensitivity analysis
• To assess improvement of disease-related symptoms and quality of life
• To assess the safety of DCC-2618
Exploratory Objectives:
• To assess the efficacy of DCC 2618 in patients after dose escalation to DCC 2618 150 mg twice daily (BID)
• To characterize KIT and PDGFRA gene resistance mutations (and potentially other gene mutations) and their DCC 2618-driven longitudinal mutation allele frequency changes in plasma cell free DNA (cfDNA)
• To retrospectively correlate KIT and PDGFRA mutation/s and/or their frequency (as well as of potentially other gene mutations) in baseline cfDNA with clinical benefit
• To understand potential tyrosine kinase inhibitor (TKI) resistance mechanisms of GIST at time of progression
• To determine concordance between KIT, PDGFRA, and other genetic mutations in tumor and cfDNA at baseline
• To assess healthcare utilization in patients with advanced GIST who have received approved therapies

Study design

This is a 2 arm, randomized, placebo-controlled, double blind, international, multicenter study comparing the efficacy of DCC 2618+best supportive care (hereafter referred to as *DCC 2618*) to placebo+best supportive care (hereafter referred to as *placebo*) in patients with advanced gastrointestinal stromal tumors (GIST) who have received treatment with prior anticancer therapies. Prior anticancer therapies must include treatment with imatinib, sunitinib, and regorafenib (3 prior therapies). Up to 40% of enrolled patients may have received prior treatment with imatinib, sunitinib, regorafenib, and other drugs (>=4 prior therapies).Approximately 120 patients will be randomized in a 2:1 ratio to DCC 2618 150 mg once daily (QD) or placebo (see Figure 1). Randomization will be stratified by:
• Patients who have received 3 prior anticancer treatments versus patients who have received >=4 prior anticancer treatments
o It should be noted that enrollment for patients who have received >=4 prior anticancer treatments will be limited to 40% of the overall sample size.
• Eastern Cooperative Oncology Group (ECOG) performance status (PS)=0 versus ECOG PS=1 or 2
The primary response for the study will be evaluated using the modified Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 - GIST specific (hereafter referred to as *modified RECIST*) based on independent radiologic review.
Upon disease progression by modified RECIST based on independent radiologic review, study drug treatment will be unblinded. At that time:
• Patients randomized to DCC 2618 150 mg QD will be given the option to:
o continue DCC 2618 at an increased dose of 150 mg BID, or
o continue treatment on study with the same dose if the Investigator feels the patient is receiving benefit from DCC 2618 or if dose escalation may not be tolerable for the patient (dose escalation is not permitted at a later time during the study), or
o discontinue DCC 2618.
• Patients randomized to placebo will be given the option to:
o cross over to receive DCC 2618 150 mg QD, or
o discontinue the study.
Patients randomized to placebo who cross over to receive DCC 2618 150 mg QD and have disease progression by modified RECIST based on Investigator assessment will be given the option to:
o continue DCC-2618 at an increased dose of 150 mg BID, or
o continue treatment on study with the same DCC 2618 dose if the Investigator feels the patient is receiving benefit from DCC 2618 or if dose escalation may not be tolerable for the patient (dose escalation is not permitted at a later time during the study), or
o discontinue DCC 2618.

Intervention

This is a 2-arm, randomized, placebo-controlled, double-blind, international, multicenter
study comparing the efficacy of DCC-2618 to placebo in patients who have received
treatment with prior anticancer therapies. Prior anticancer therapies must include treatment
with imatinib, sunitinib, and regorafenib (3 prior therapies). Up to 40% of enrolled patients
may have received prior treatment with imatinib, sunitinib, regorafenib, and other drugs (>=4
prior therapies). Approximately 120 patients will be randomized in a 2:1 ratio to DCC-2618
150 mg QD or placebo. Randomization will be stratified by:
• Patients who have received 3 prior anticancer treatments versus patients who have
received >=4 prior anticancer treatments
• It should be noted that enrollment for patients who have received >=4 prior anticancer
treatments will be limited to 40% of the overall sample size.
• Eastern Cooperative Oncology Group (ECOG) performance status (PS)=0 versus ECOG
PS=1 or 2
The primary response for the study will be evaluated using the modified RECIST Version 1.1
- GIST-specific (hereafter referred to as *modified RECIST*) based on independent
radiologic review.
Upon disease progression by modified RECIST based on independent radiologic review,
study drug treatment will be unblinded. At that time:
Patients randomized to DCC-2618 150 mg QD will be given the option to:
• continue DCC-2618 at an increased dose of 150 mg BID, or
• continue treatment on study with the same dose if the Investigator feels the patient is
receiving benefit from DCC-2618 or if dose escalation may not be tolerable for the
patient (dose escalation is not permitted at a later time during the study), or
• discontinue DCC-2618.
Patients randomized to placebo will be given the option to:
• cross over to receive DCC-2618 150 mg QD, or
• discontinue the study.
Patients randomized to placebo who cross over to receive DCC-2618 150 mg QD and have disease progression by modified RECIST based on Investigator assessment will be
given the option to:
• continue DCC-2618 at an increased dose of 150 mg BID,
• continue treatment on study with the same DCC-2618 dose if the Investigator

feels
the patient is receiving benefit from DCC-2618 or if dose escalation may not be tolerable for the patient (dose escalation is not permitted at a later time during the
study), or,
• discontinue DCC-2618

Study burden and risks

The side effects may be mild, moderate, severe, long-lasting, permanent or fatal. Many side effects may go away shortly after the drug is stopped, but in some cases, side effects can last longer. Sometimes they can be permanent or serious. DCC-2618 is still being studied in humans and not all the side effects are known. There is a risk of a rare or previously unknown side effect occurring.

As of August 2018, 227 patients with different types of cancer have received DCC-2618 in the Phase 1 study. The followings side effects have been reported. These side effects may or may not be related to DCC-2618. Some may have been considered serious.
Common side effects reported in more than 20% of patients:
• Fatigue (40%)
• Hair loss (39%)
• Pain or ache in the muscle (34%)
• Constipation (29%)
• Hand-Foot-Syndrome (blisters, redness, swelling, and pain on the palms of hands and/or the soles of the feet, 26%)
• Nausea (25%)
• Loss of appetite (23%)
• High blood levels of an enzyme that breaks down fat (22%)
Occasional side effects reported 20% or less of patients:
• Weight loss (20%)
• Abdominal pain (18%)
• Diarrhea (17%)
• Vomiting (16%)
• Decreased iron in the blood, which may make you feel tired or short of breath (15%)
• Joint pain (15%)
• High blood pressure (15%)
• Shortness of breath (15%)
• Rash (14%)
• Headache (13%)
• Dry skin (12%)
• Increased levels of blood bilirubin, which is a pigment produced by the liver. Increased levels can cause possible yellowing of the skin and/or eyes and may indicate liver injury (12%)
• Pain in extremity (12%)

• Cough (11%)
• Muscle spasms (11%)

Some side-effects were considered serious (e.g., required hospitalization or the doctor felt they were medically important). The following is a list of serious side effects reported in 2 or more patients. They may or may not be related to DCC-2618.
• In 8 patients (4%): abdominal pain
• In 6 patients (3%): shortness of breath
• In 4 patients (2%): fever
• The following side effects were reported in 3 patients (1%) each: intestinal blockage, life-threatening blood infection, urinary tract infection, decreased iron in the blood, increased bilirubin, confusion
• The following side effects were reported in 2 patients (1%) each: fluid accumulation in the belly, trouble swallowing, intestinal bleeding, pneumonia, inflammation of the pancreas, vomiting, fatigue, increased levels of an enzyme that breaks down fat, mental status changes, chest pain, heart failure, blood clots, low blood pressure, kidney failure, falls

One patient treated with DCC-2618 was diagnosed with Stevens-Johnson Syndrome and recovered once the drug was stopped. It is a rare, serious disorder of the skin and mucous membranes. It begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters. Then, the top layer of the affected skin dies, sheds and then heals. This is a serious condition and may be life-threatening.
While deaths have been reported on the Phase 1 study, none were related to DCC-2618 treatment. As of August 2018, thirty patients died during the study with most (22 patients) having died due to disease progression. Three patients died suddenly due to heart failure. One patient died due to an infection of the bile duct and one died due to cardiac arrest. Three patients died to unknown reasons.

Skin Side Effects Observed in Participants in the Phase 1 study that May be Related to DCC-2618
Some patients treated with DCC-2618 to date have reported changes in the skin. As of August 2018, eleven (11) patients have had; a curable form of skin cancer (squamous cell carcinoma). This was treated by removing the tumors using an outpatient surgical procedure. This common cancer tends to occur in sun exposed skin and can be seen with the naked eye as often, dry, flaky, raised or depressed, slow-growing bumps in the skin. Other reported skin changes that are not listed above were non-cancerous or pre-cancerous skin lesions (including actinic keratosis and keratoacanthoma) reported in 13 other patients.

Risks for Patients with Lactose Intolerance: Study drug pills contain lactose; therefore, patients with lactose intolerance should discuss this with their study doctor.

Possible Drug Interaction Risks: The combination of study drug and any other medications could be harmful.

Blood Draw Risks: Blood draws may cause pain, bleeding, and/or bruising.

Tumor Biopsy Risks: Risks associated with biopsy of tumor include bleeding, pain, and infection.

ECG Risks: The tape used to adhere the electrodes to skin may cause some redness and/or swelling.

CT Scan Risks: The dye used in CT scans may cause pain, burning sensation, hot flushes, and a severe allergic reaction, particularly in those with prior allergies to iodine.

MRI Risks: The dye used for MRIs may cause headache, nausea, stomach pain, and convulsions. There is the possibility of a severe allergic reaction that may be life threatening.

Pregnancy Risks: The effects of DCC-2618 on the reproductive system (sperm, eggs), nursing infant, or the unborn child are not known and may be harmful.

Phototoxicity Risks: Your skin may be more sensitive to sunlight while taking DCC-2618.

There may be additional risks that are unknown or unexpected.

The researchers have taken steps to minimize the risks of this study.

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. Male or female patients >=18 years of age at the time of informed consent
2. Histologic diagnosis of GIST
3.Patients must have progressed on imatinib, sunitinib, and regorafenib or have documented intolerance to any of these treatments despite dose modifications.
4. ECOG PS of 0 to 2 at screening.
5. Able to provide an archival tumor tissue sample if no anticancer therapy was administered since the sample was collected; otherwise, a fresh tumor tissue sample is required prior to the first dose of study drug.
6. Female patients of childbearing potential must have a negative serum beta-human chorionic gonadotrophin (β-hCG) pregnancy test at screening and a negative pregnancy test at Cycle 1 Day 1 prior to the first dose of study drug.
7. Patients of reproductive potential must agree to follow the contraception requirements outlined in Section 6.11.10 of the study protocol.
8. The patient is capable of understanding and complying with the protocol and has signed the informed consent document. A signed informed consent form must be obtained before any study-specific procedures are performed.
9. At least 1 measurable lesion according to modified RECIST Version 1.1 (non-nodal lesions must be >=1.0 cm in the long axis or >=double the slide thickness in the long axis) within 21 days prior to the first dose of study drug.
10. Adequate organ function and bone marrow reserve as indicated by the following laboratory assessments performed at screening.
• Absolute neutrophil count >=1000/µL
• Hemoglobin >=8 g/dL
• Platelet count >=75,000/µL
• Total bilirubin <=1.5 x the upper limit of normal (ULN)
• Aspartate transaminase and alanine transaminase <=3 x ULN (<=5x ULN in the presence of hepatic metastases)

• Serum creatinine <=1.5 x ULN or creatinine clearance >=50 mL/min based on either urine collection or Cockcroft Gault estimation.
• Prothrombin time (PT), international normalized ratio (INR), and partial thromboplastin time <=1.5 x ULN. Patients on a stable, maintenance regimen of anticoagulant therapy for at least 30 days prior
to study drug administration may have PT/INR measurements >1.5 x ULN if, in the opinion of the Investigator, the patient is suitable for the study. An adequate rationale must be provided to the
Sponsor prior to randomization.
11. Resolution of all toxicities from prior therapy to <=Grade 1 (or baseline) within 1 week prior to the first dose of study drug (excluding alopecia and <=Grade 3 clinically asymptomatic lipase, amylase, and creatine phosphokinase laboratory abnormalities).

Exclusion criteria

1. Treatment with anticancer therapy, including investigational therapy, or investigational procedures within 14 days or 5 x the half life (whichever is longer) prior to the first dose of study drug. For prior biological therapies, eg, monoclonal antibodies with a half life longer than 3 days, the interval must be at least 28 days prior to the first dose of study drug.
2. Prior treatment with DCC-2618.
3. Prior or concurrent malignancy whose natural history or treatment have the potential to interfere with the safety or efficacy assessment of DCC-2618. Patients receiving adjuvant cancer treatment are not eligible if those medications are potentially active against GIST or excluded per protocol (refer to Section 5.12.3 of the protocol).
4. Patient has known active central nervous system metastases.
5. New York Heart Association class II - IV heart disease, active ischemia or any other uncontrolled cardiac condition such as angina pectoris, clinically significant cardiac arrhythmia requiring therapy, uncontrolled hypertension or congestive heart failure.
6. Arterial thrombotic or embolic events such as cerebrovascular accident (including ischemic attacks) or hemoptysis within 6 months before the first dose of study drug.
7. Venous thrombotic events (eg, deep vein thrombosis) or pulmonary arterial events (eg, pulmonary embolism) within 3 months before the first dose of study drug. Patients with venous thrombotic events >=3 months before the first dose of study drug on stable anticoagulation therapy are eligible.
8. 12 lead electrocardiogram (ECG) demonstrating QT interval corrected by Fridericia*s formula >450 ms in males or >470 ms in females at screening or history of long QT interval corrected syndrome.
9. Left ventricular ejection fraction (LVEF) <50% at screening.
10. Use of proton-pump inhibitors within 4 days prior to the first dose of study drug. Other medications that increase gastric pH, ie, histamine H2

receptor antagonists and antacids may be taken provided they are not administered within 2 hours before or after administration of study drug.
11. Use of strong or moderate inhibitors and inducers of cytochrome P450 (CYP) 3A4, including certain herbal medications (eg, St. John*s Wort) and consumption of grapefruit or grapefruit juice within 14 days or 5 x the half life (whichever is longer) prior to the first dose of study drug. Please refer to the Indiana University Department of Medicine website (http://medicine.iupui.edu/clinpharm/ddis/main-table/) for guidance on medications that inhibit CYP3A4 enzymes.
12 Use of known substrates or inhibitors of breast cancer resistance protein (BCRP) transporters within 14 days or 5 x the half life (whichever is longer) prior to the first dose of study drug. Please refer to the US Food and Drug Administration*s (FDA) website (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm) for inhibitors and substrates.
13. Major surgeries (eg, abdominal laparotomy) within 4 weeks of the first dose of study drug. Following major surgeries, >4 weeks prior to the first dose of study drug, all surgical wounds must be healed and free of infection or dehiscence.
14. Any other clinically significant comorbidities, such as uncontrolled pulmonary disease, active infection, or any other condition, which in the judgment of the Investigator, could compromise compliance with the protocol, interfere with interpretation of the study results, or predispose the patient to safety risks.
15. Known human immunodeficiency virus or hepatitis C infection only if the patient is taking medications that are excluded per protocol (refer to Section 5.12.3), active hepatitis B, or active hepatitis C infection.
16. If female, the patient is pregnant or lactating.
17. Known allergy or hypersensitivity to any component of the investigational drug product. Patients with a history of Stevens-Johnson syndrome on a prior TKI are excluded.
18. Gastrointestinal abnormalities including but not limited to:
• inability to take oral medication
• malabsorption syndromes
• requirement for intravenous alimentation
19. Any active bleeding excluding hemorrhoidal or gum bleeding

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:	Completed
Start date (anticipated):	20-09-2018
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	DCC-2618
Generic name:	na

Ethics review

Approved WMO

Date:	08-01-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	10-09-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	08-10-2018
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-07-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	12-08-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-12-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.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
EudraCT	EUCTR2017-002446-76-NL
CCMO	NL64347.058.17

Study results

Date completed: 10-11-2020

Results posted: 13-01-2023

Summary results
Trial ended prematurely

First publication
13-11-2019