A Phase 1/2, open-label, single arm, multicohort, multicenter trial to evaluate the safety and efficacy of JCAR017 in pediatric subjects with relapsed/refractory (r/r) B-cell acute lymphoblastic leukemia (B-ALL) and B-cell non-Hodgkin lymphoma (B-NHL) (TRANSCEND PEDALL)

Published: 08-08-2018
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Phase 1:To identify the recommended Phase 2 dose (RP2D) of JCAR017 in pediatric subjects withCD19+ r/r B-ALL.Phase 2:To evaluate the following efficacy endpoints of the JCAR017 RP2D identified in Phase 1, in the following three diseasecohorts:•...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON48667

Source
ToetsingOnline

Brief title
0451-0335
JCAR017-BCM-004
TRANSCEND PEDALL

Condition

- Lymphomas non-Hodgkin's B-cell
- Leukaemias

Synonym
relapsed/refractory B-cell acute lymphoblastic leukemia and B-cell non-Hodgkin lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Celgene Corporation
Source(s) of monetary or material Support: The study sponsor as listed in question B6/B7

Intervention

Keyword: JCAR017, Pediatric, Phase 1/2, r/r B-ALL and B-NHL

Outcome measures

Primary outcome

Phase 1

Recommended Phase 2 dose (RP2D). Identify pharmacokinetic (PK), and number of

subjects experiencing a dose-limiting toxicity (DLT).

Phase 2 - Cohort 1

(relapsed/refractory [r/r] B-cell acute lymphoblastic leukemia [B-ALL]):

Overall response rate (ORR). Percentage of subjects achieving a confirmed

complete response (CR) or complete response with incomplete blood count

recovery (CRi)

Phase 2 - Cohort 2

(MRD+ BALL): Minimal residual disease (MRD) negative (MRD-) rate.

Percentage of subjects achieving a confirmed MRD negative rate

Phase 2 - Cohort 3

(r/r B-cell non-Hodgkin lymphoma [BNHL]): Overall response rate (ORR).

Percentage of subjects achieving CR or partial response (PR)

Secondary outcome

1. Safety - Type, frequency, and severity of adverse events (AEs), including

serious adverse events (SAEs) and laboratory abnormalities

2. Feasibility of manufacturing JCAR017 (Phase 1 only) - Percentage of JCAR017

product generated successfully

3. Overall response rate (ORR) in the non-selected dose from Phase 1 -

Percentage of subjects achieving a confirmed CR or Cri

4. Duration of response (DOR) - Time from first response until progressive

disease (PD), disease relapse, or death from any cause, whichever occurs first

5. Relapse-free survival (RFS) - Time from first response to documentation of

PD, disease relapse, or death due to any cause, whichever occurs first

6. Best overall response (BOR)

7. Event-free survival (EFS) - Time from JCAR017 infusion to PD, disease relapse, start of a new anticancer therapy, or death from any cause, whichever occurs first

8. Overall survival (OS) - Time from JCAR017 infusion to time of death due to any cause

9. MRD response rate (non-selected RP2D cohort in Phase 1 and Cohort 1 in Phase 2 only) - Percentage of subjects achieving a CR or CRi and a negative MRD bone marrow

10. Rate of hematopoietic stem cell transplant (HSCT) after response to JCAR017 infusion - Percentage of subjects who achieve a response after JCAR017 infusion and then proceed to HSCT

11. Pharmacokinetics (PK) - Maximum concentration (Cmax), time to peak concentration (Tmax), area under the curve (AUC), including maximum expansion and duration of persistence of JCAR017

Study description

Background summary

CD19 as a Therapeutic Target
CD19 is a 95 kDa glycoprotein present on B-cells from early development until differentiation into plasma cells. It is a member of the immunoglobulin superfamily and functions as a positive regulator of the B-cell receptor by

lowering the signaling threshold for B-cell activation. CD19 is an attractive therapeutic target because it is expressed by most B-cell malignancies, including BNHL. Importantly, the CD19 antigen is not expressed on hematopoietic stem cells or on any normal tissue apart from those of the B-cell lineage. Additionally, CD19 is not shed in the circulation, which limits off-target adverse effects.

CD19-Targeted Chimeric Antigen Receptors
CD19-specific CARs are generated by the fusion of a single chain variable fragment (scFv), derived from an anti-CD19 monoclonal antibody (mAb), to an intracellular signaling domain. Expression of the CD19-directed CAR in autologous T cells is achieved by ex vivo transduction
using a recombinant retroviral or lentiviral vector. The CAR is expressed on the T cell surface and redirects the transfected T cells to CD19-expressing lymphoma cells, leading to CD19- specific tumor cell recognition, lysis, cytokine secretion, and T cell proliferation. In clinical studies, CD19-targeted CARs have demonstrated encouraging activity in adult and pediatric subjects with r/r B-ALL and B-NHL.

CD19 CAR T cell therapy is an effective adoptive cell treatment and has the potential to overcome chemo-refractory B-cell leukemia and lymphoma, as demonstrated in the ELIANA clinical study and recent approval of Kymriah in the US.

JCAR017 Investigational Drug Product
The final JCAR017 investigational drug product being evaluated in this study includes two
individually formulated CD4+CAR+ and CD8+ CAR+ --- T cell suspensions in media containing dimethyl sulfoxide (DMSO) that are thawed and infused separately. JCAR017 is
administered by IV infusion.

The CD19-specific CAR and truncated human epidermal growth factor receptor (EGFRt) are introduced into autologous CD8+ and CD4+ T cells ex vivo using a replication-incompetent,self-inactivating lentiviral vector. The CD19-specific CAR includes an scFv binding domain
derived from a murine CD19-specific monoclonal antibody (mAb; FMC63) and 4-1BB and CD3* chain signaling domains. The EGFRt protein is expressed as a separate cell surface protein for purposes of cell tracking.

Refer to the Investigator*s Brochure (IB) for detailed information concerning the available pharmacology, toxicology, drug metabolism, clinical studies, and adverse event (AE) profile of the investigational product (IP).

Study objective

Phase 1:
To identify the recommended Phase 2 dose (RP2D) of JCAR017 in pediatric subjects with
CD19+ r/r B-ALL.

Phase 2:
To evaluate the following efficacy endpoints of the JCAR017 RP2D identified in Phase 1, in the following three disease
cohorts:
• Cohort 1 (r/r B-ALL): Overall response rate (ORR) defined as proportion of subjects with
complete response (CR) or complete response with incomplete blood count recovery (CRi) on Day 28 that must be confirmed on Day 56
• Cohort 2 (MRD [minimal residual disease] positive [MRD+] B-ALL): MRD negative rate defined as proportion of subjects with a negative MRD (MRD-) response on Day 28
that must be confirmed on Day 56
• Cohort 3 (r/r B-NHL [DLBCL, BL, or PMBCL]): ORR defined as proportion of subjects
with a CR or partial response (PR) on Day 28

Study design

This is a Phase 1/2, open-label, single arm, multicohort study incorporating the mTPI-2 dose escalation design in Phase 1 and a Simon*s Optimal two-stage design in Phase 2 to evaluate the safety and efficacy of JCAR017 in pediatric subjects with CD19+ r/r B-ALL and B-NHL--.

Phase 1
Up to 5 dose levels of JCAR017 will be evaluated.
Enrollment will commence in pediatric subjects with r/r B-ALL at Dose Level 1 (DL1) of 0.05x106 chimeric antigen receptor (CAR)+ T cells/kg (maximum DL1 of 5x106 JCAR017 CAR+ T cells [non-weight adjusted]). If this dose is confirmed to be safe and tolerable, additional subjects will be enrolled at higher dose(s) up to 0.75 x106 CAR+ T cells/kg (maximum of 75x106 JCAR017 CAR+ T cells [non-weight adjusted]) with the aim to identify the RP2D. Dose escalation/de-escalation will follow a modified toxicity probability interval (mTPI-2) algorithm with a target dose limiting toxicity (DLT) rate of 30% and an equivalence interval of 25% to 35%. A dose level will be considered unsafe, with no additional pediatric subjects enrolled at that dose level, if it has an estimated 95% or more probability of exceeding the target DLT rate of 30% (ie, P (DLT > 30%|data) > 95%) with at least 3 pediatric subjects treated at that dose level. For a dose level to be declared safe per the mTPI-2 algorithm, at least 3 DLT-evaluable pediatric subjects must have completed the DLT period and

the level estimated to be safe.
Once the RP2D for JCAR017 has been selected, additional subjects will be enrolled until at least 10 pediatric subjects are treated at the identified RP2D. The final number of pediatric subjects enrolled and treated, will depend on the number of dose levels tested and the number of DLTs observed within each dose level.
A Safety Review Committee (SRC) will convene regularly during Phase 1 to review DLTs) and recommend a Phase 2 dose based on an integrated assessment of the safety, pharmacokinetic (PK) data and preliminary efficacy information from at least 10 pediatric subjects treated at the RP2D. Analysis of the JCAR017 manufactured product may also be considered.

Phase 2
Up to 71 primary endpoint evaluable pediatric subjects (< 18 years of age) will be treated at the RP2D in one of the 3 cohorts listed below. The sample size for Cohorts 1 and 2 is calculated according to Simon*s Optimal two-stage design and based on the primary endpoints of ORR (Cohorts 1 and 3) and MRD negative rate (Cohort 2).
The 10 or more pediatric subjects treated at the RP2D in Phase 1 will form part of the sample size (ie, Cohort 1 and Cohort 2). Therefore, the protocol intends to treat 81 primary endpoint evaluable pediatric subjects in Phase 2, if warranted by the evaluation of results at the completion of the first stage of the study in each cohort. 8.
• Cohort 1: 48 r/r B-ALL evaluable pediatric subjects (13 subjects in Stage 1 and 35 subjects in Stage 2)
• Cohort 2 : 23 MRD+ B-ALL evaluable pediatric subjects (9 subjects in Stage 1 and 14 subjects in Stage 2)
• Cohort 3: 10 r/r B-NHL (DLBCL, BL, or PMBCL) evaluable pediatric subjects (due to the very low incidence rate and therefore expected low subject accrual, there is no formal sample size for this arm).
Celgene may elect to explore the identified RP2D in up to 20 additional B-ALL subjects between 18 and 25 years of age in an optional cohort in Phase 2, if it is determined that the risk-benefit profile is such that exploration is warranted after consultation with the SRC.

Intervention

Following enrollment in the study, an unstimulated leukapheresis collection will be performed
on each subject to obtain a sufficient quantity of peripheral blood mononuclear cells (PBMCs)
for the production of the JCAR017 investigational product (IP).

Subjects will receive 3 days of fludarabine intravenously (IV) (30 mg/m2) and cyclophosphamide
IV (300 mg/m2) for LD chemotherapy. Two to 7 days after completion of LD chemotherapy,

JCAR017 will be administered by IV infusion as a single dose on Day 1. The final JCAR017
drug product consists of two individually formulated CD4+ CAR+ and CD8+ CAR+ frozen T
cell suspensions administered in a 1:1 ratio in a formulation containing dimethyl sulfoxide
(DMSO).

In Phase 1, up to 5 dose levels of JCAR017 will be evaluated. The first dose level will be 0.05x106 CAR+ T cells/kg (maximum dose of 5x106 JCAR017 CAR+ T cells [non-weight adjusted]). The declared RP2D will be applied in Phase 2. JCAR017 dosing will be capped at 100kg for all dose levels.

Study burden and risks

Participation in the study will involve risks from the study procedures, from treatment with lymphodepleting chemotherapy and from treatment with JCAR017. The two most significant side effects that have been observed to occur with genetically modified T cells in previous studies are cytokine release syndrome (CRS) and neurologic toxicity.

Participation in the study also means additional time from participants (up to 24 hospital visits), additional or longer hospital stays, additional tests and instructions to be followed.

Although, the risks are significant for the participating subjects, they are acceptable when balanced against the anticipated efficacy of JCAR017 in this disease population provided that there is meticulous clinical management.

JCAR017 offers substantial potential clinical activity to the patients. Current clinical (in clinical studies, CD19-targeted CARs) have demonstrated encouraging activity in adult and pediatric subjects with R/R B-cell acute lymphoblastic leukemia (ALL) and B-cell NHL. The remission rate for subjects treated with JCAR017 significantly improved compared to historical data. Therefore, JCAR017 may provide an opportunity to increase the rates and duration of remissions thereby potentially extending survival for a population with historically dismal clinical outcomes. Currently available treatments have limited activity.

Despite recent advances in the treatment of B-cell malignancies, many patients relapse or have refractory disease and remain incurable with current treatment options. Novel therapies are therefore urgently needed.

In conclusion, the current benefit-risk profile for JCAR017 after administration of the lymphodepleting chemotherapy is considered acceptable in the proposed clinical study given the potential for a durable remission, the overall manageable safety profile, and the

plan for risk mitigation of potential safety concerns associated with JCAR017 administration, including routine trial safety surveillance practices.

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)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1. Phase 1: Subject < 18 years of age and weighs >= 6 kg at the time of signing the informed consent form (ICF)/informed assent form (IAF). Phase 2: Subject <= 25 years of age and weighs >= 6 kg at the time of signing the ICF/IAF
2. Subject (when applicable, parental/legal representative) must understand and voluntarily provide permission to the ICF/IAF prior to conducting any

study-related assessments/procedures.
3. Subject is willing and able to adhere to the study visit schedule and other protocol requirements.
4. Investigator considers the subject is appropriate for adoptive T cell therapy.
5. Evidence of CD19 expression via flow cytometry (peripheral blood or bone marrow) or immunohistochemistry (bone marrow biopsy)
6. Subject has a Karnofsky score of >= 50 (subjects >= 16 years of age) or a Lansky score >= 50 (subjects < 16 years of age).
7. Diagnosis of B-cell ALL or B-cell NHL as defined below: Phase 1:
- Phase 1: Subjects with r/r B-ALL, defined as morphological evidence of disease in BM (5% or greater lymphoblast by morphology) and either of the following: First or greater marrow relapse, or, Any marrow relapse after allogeneic HSCT, or, Primary refractory defined as not achieving a CR or a CRi after 2 or more separate induction regimens (or chemo-refractory as not achieving CR/CRi after 1 cycle of standard chemotherapy for relapsed leukemia), or, Ineligible for allogeneic HSCT. -
Phase 2: Subjects with one of the following:, Cohort 1: r/r B-ALL, defined as morphological evidence of disease in BM (5% or greater lymphoblast by morphology) and either:, First or greater marrow relapse, or, Any marrow relapse after allogeneic HSCT, or, Primary refractory defined as not achieving a CR or a CRi after 2 or more separate induction regimens (or chemo-refractory as not achieving CR/CRi after 1 cycle of standard chemotherapy for relapsed leukemia), or, Ineligible for allogeneic HSCT.
Cohort 2: MRD+ B-ALL, defined as: less as 5% lymphoblasts by morphology with, MRD detected by a validated assay at a frequency of 1 x10-4 or greater in BM cells. Subjects eligible for enrollment in Cohort 2 are those with MRD positive morphologic CR2 after re-induction when these subjects had previously experienced an early relapse (< 36 months) after first-line chemotherapy. Subjects who are in MRD+ morphologic CR3 and later, regardless of time to relapse in earlier lines, are also eligible. Subjects who are in morphologic relapse at screening (r/r B-ALL) and become MRD+ after bridging chemotherapy are also eligible for treatment in Cohort 2.
Cohort 3: r/r B-NHL (DLBCL, BL or PMBCL), defined as Measurable disease after 1 or more lines of chemotherapy and/or having failed HSCT or being ineligible for HSCT. Note: B-NHL subjects with secondary CNS lymphoma involvement are eligible however subject selection must consider clinical risk factors for severe neurological AEs and alternative treatment options. Subjects should only be enrolled if the Investigator considers the potential benefit outweighs the risk for the subject.
8. Subjects with Philadelphia chromosome positive ALL are eligible if they are intolerant to or have failed one or more lines of tyrosine-kinase inhibitor (TKI) therapy or if TKI therapy is contraindicated.
9. Adequate organ function, defined as: Adequate BM function to receive LD chemotherapy as assessed by the Investigator. Subject with adequate renal function, which is defined as Subjects that do not meet the criteria but who have a creatinine clearance or radioisotope glomerular filtration rate (GFR) of

more than 70 mL/min/1.73 m2 are eligible. Alanine aminotransferase (ALT) <= 5 x upper limit of normal (ULN) and total bilirubin less than 2.0 mg/dL (or less than 3.0 mg/dL for subjects with Gilbert*s syndrome or, leukemic/lymphomatous infiltration of the liver)., Adequate pulmonary function, defined as <= Grade 1 dyspnea according to Common Toxicity Criteria for Adverse Events (CTCAE) and oxygen saturation (SaO2) >= 92% on room air., Adequate cardiac function, defined as left ventricular ejection fraction (LVEF) >= 40% as assessed by echocardiogram (ECHO) or multi-gated acquisition scan (MUGA) within 4 weeks prior to leukapheresis.
10. Adequate vascular access for leukapheresis procedure.
11. Subjects must agree to not donate blood, organs, sperm or semen, and egg cells for usage in other individuals for at least 1 year following LD chemotherapy. There are insufficient exposure data to provide any recommendation concerning the duration of refraining from tissue donation following treatment with JCAR017. Therefore, subjects treated with JCAR017 should not donate blood, organs, tissues and cells for transplantation.
See protocol for more inclusion criteria

Exclusion criteria

1. Subject has any significant medical condition, laboratory abnormality, or psychiatric illness that would prevent the subject from participating in the study., 2. Subject has any condition including the presence of laboratory abnormalities, which places the subject at unacceptable risk if he/she were to participate in the study., 3. Subject has any condition that confounds the ability to interpret data from the study., 4. Subject with a history of another primary malignancy that has not been in remission for at least 2 years prior to enrollment., 5. Subjects who have received previous CD19-targeted therapy must have CD19-positive disease confirmed since completing the prior CD19-targeted therapy., 6. Prior CAR T cell or other genetically-modified T cell therapy., 7. Subject with a previous history of or active hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) infection., 8. Subjects with uncontrolled systemic fungal, bacterial, viral or other infection (including tuberculosis) despite appropriate antibiotics or other treatment at the time of leukapheresis or JCAR017 infusion., 9. Subject has presence of acute or chronic graft-versus-host disease (GVHD)., 10. Subject with active autoimmune disease requiring immunosuppressive therapy., 11. Subject has cardiac disorders (CTCAE version 4.03 Grade 3 or 4) within the past 6 months., 12. Subject with a concomitant genetic syndrome, with the exception of Down*s syndrome., 13. Subject with active CNS disease and significant neurological deterioration. Subjects with CNS-2 or CNS-3 involvement are eligible provided they are asymptomatic and do not have significant neurological deterioration and, in the opinion of the study investigaton --- 14. Subject with a history or presence of clinically relevant CNS pathology --- 15. Subject is pregnant or nursing., 16. Subject has used the following:, Therapeutic doses of corticosteroids (defined

as > 0.4 mg [maximum]) within 7 days prior to leukapheresis or 72 hours prior to JCAR017 infusion. Physiologic replacement, topical, and inhaled steroids are permitted., Low-dose chemotherapy (eg, vincristine, rituximab, cyclophosphamide <= 300 mg/m2) given after leukapheresis to maintain disease control must be stopped >= 7 days prior to LD chemotherapy. Cytotoxic chemotherapeutic agents that are not considered lymphotoxic (see below) within 1 week prior to leukapheresis. Oral anticancer agents --- are allowed if at least 3 half-lives have elapsed prior to leukapheresis. Lymphotoxic chemotherapeutic agents (eg, cyclophosphamide, ifosfamide, bendamustine) within 2 weeks prior to leukapheresis., Experimental agents within 4 weeks prior to leukapheresis unless no response or PD is documented on the experimental therapy and at least 3 half-lives have elapsed prior to leukapheresis., Immunosuppressive therapies within 4 weeks prior to leukapheresis and JCAR017 infusion (eg, calcineurin inhibitors, methotrexate or other chemotherapeutics, mycophenolate, rapamycin, thalidomide, immunosuppressive antibodies such as antitumor necrosis factor [TNF], anti-IL-6, or anti-IL-6R)., Donor lymphocyte infusions (DLI) within 6 weeks prior to JCAR017 infusion., Radiation within 6 weeks prior to leukapheresis. Subjects must have PD in irradiated lesions or have additional non-irradiated lesions to be eligible. Radiation to a single lesion, if additional non-irradiated, measurable lesions are present, is allowed up to 2, weeks prior to leukapheresis., Allogeneic HSCT within 90 days prior to leukapheresis. 17. Tumor invasion of venous or arterial vessels (B-NHL subjects only)
18. Deep Venous Thrombosis (DVT) or Pulmonary Embolism (PE) within3 months prior to leukapheresis. Subjects with DVT or PE that occurred longer than 3 months prior to leukapheresis, who still require ongoing therapeutic levels of anti-coagulation therapy, are also excluded. 19. Existence of CD19-negative clone(s) of leukemia cells.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2021
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	29-08-2019
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-12-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-02-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-03-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-03-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	16-07-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-09-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-10-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-04-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-05-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
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Application type:	Amendment

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Approved WMO Date:	01-10-2021
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Approved WMO Date:	10-03-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
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Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-10-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-05-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-05-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2018-001246-34-NL
ClinicalTrials.gov	NCT03743246;U1111-1220-3324
CCMO	NL66379.000.18