A Phase 1-2, Open-Label, Dose-Finding, Proof of Concept, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of CX-2009 in Adults with Metastatic or Locally Advanced Unresectable Solid Tumors

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Part A - CX-2009 Monotherapy: Every 21-Day Dosing RegimenThe primary objective of Part A is to determine the safety profile of CX-2009, the maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D), and the dose-limiting toxicities(DLTs) of CX-...

Ethical review	Approved WMO
Status	Completed
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON48575

Source
ToetsingOnline

Brief title
PROCLAIM-CX-2009

Condition

- Metastases

Synonym
Metastatic or Locally Advanced Unresectable Solid Tumors

Research involving
Human

Sponsors and support

Primary sponsor: CytomX Therapeutics, Inc.
Source(s) of monetary or material Support: CytomX Therapeutics;Inc.

Intervention

Keyword: CX-2009, Metastatic or Locally Advanced Unresectable Solid Tumors

Outcome measures

Primary outcome

The primary criteria for defining evidence of anti-cancer activity and also for management of subject care will be a clinical response as defined by RECIST (Version 1.1). Efficacy in subjects treated with the combination CX-2009 plus CX-072 (Parts D1 and D2) will be explored additionally on the basis of ORR by irRECIST as defined in the Core (Appendix A). Management of subjects in Parts D1 and D2 may take into consideration tumor response assessed by irRECIST.

Substudy:

Parameters which will be evaluated in the substudy are as follows:

- Uptake of 89Zr-CX-2009 in tumor lesions;

- Biodistribution of 89Zr-CX-2009 in normal tissues; and

- Dosimetry.

Secondary outcome

Concentration versus time data will be tabulated and plotted for the individual and mean CX-2009 (total and intact), CX-2009 conjugated DM4, and free DM4, including DM4-Me analytes and for total and intact CX-072 moieties.

Serum samples will be collected to assess the immunogenicity of CX-2009 Serum samples will be collected to assess the immunogenicity of CX-2009 and CX-072, the latter for Parts D1 and D2 only. Samples will be initially screened for ADAs.

The overall goal of the biomarker portion of CTMX-M-2009-001 is to explore A) Probody mechanistic proof of concept, and B) potential predictive markers associated with the clinical activity of CX-2009 alone or in combination with CX-072.

Study description

Background summary

CytomX has developed an anti-human CD166 Probody-Therapeutics, termed CX-2009, selected for specific binding, internalization, and ability to elicit cytotoxicity. In addition, CX-2009 exhibits cross reactivity to cynomolgus monkeys, thus facilitating safety assessments in this species. CX-2009 is a humanized, IgG1 isotype N-succinimidyl 4-(2-pyridyldithio) butanoate-N2*-Deacetyl-N2*-(4mercapto-4-methyl-1-oxopentyl)-maytansine (SPDB-DM4) drug conjugate and has been tested in nonclinical models for efficacy and safety. Treatment with CX-2009 at therapeutically relevant doses has led to significant tumor growth inhibition or regression in models of multiple tumor types including: lung, breast, ovarian, head and neck squamous cell carcinoma (HNSCC), and cholangiocarcinoma (CCC). These same doses were demonstrated to be well-tolerated in cynomolgus monkeys.

Substudy:
Molecular radionuclide imaging with PET will be used as an approach to optimize clinical insight into the pharmacokinetics (PK), target engagement, tumor selectivity, and heterogeneity of tumor targeting of CX-2009.

Subjects will be administered 37 MBq of 89Zr-CX-2009 IV as several studies have

shown that
administration of 37 MBq of 89Zr-labeled antibodies is feasible and safe, and that the procedure
allows for quantitative assessment of uptake in target lesions and whole body distribution.

Study objective

Part A - CX-2009 Monotherapy: Every 21-Day Dosing Regimen
The primary objective of Part A is to determine the safety profile of CX-2009, the maximum
tolerated dose (MTD)/recommended Phase 2 dose (RP2D), and the dose-limiting toxicities
(DLTs) of CX-2009, when administered intravenously (IV) every 21 days as monotherapy to
subjects with selected advanced or recurrent solid tumors.

Part A2 - CX-2009 Monotherapy: Every 21-Day Dosing Regimen
The primary objectives of Part A2 are to determine the following in subjects treated with CX-2009:
• Characterize the protease activity and measure the cleavage of CX-2009 in tumor
biopsies and peripheral blood in subjects with demonstrated high tumor expression of
CD166 by immunohistochemistry (IHC); and
• Obtain additional characterization of the safety of CX-2009 when administered as
monotherapy at dose levels evaluated in Part A.

Part B - CX-2009 Monotherapy: Every 21-Day Dosing Regimen
The primary objective of Part B is to evaluate the efficacy of CX-2009 when administered IV
every 21 days as monotherapy at the MTD/RP2D (as defined in consideration of available data
from Part A and Part A2) in subjects with selected advanced or recurrent solid tumors andwith
demonstrated high tumor expression of CD166 by IHC. Efficacy will be assessed on the basis of
the Objective Response Rate (ORR) by the Response Evaluation Criteria in Solid Tumours
(RECIST) Version 1.1.

Part C1 - CX-2009 Monotherapy: Every 14-Day Dosing Regimen
The primary objective of Part C1 is to determine the safety profile of CX-2009, the MTD/RP2D,
and the DLTs of CX-2009 when administered IV every 14 days as monotherapy to subjects with

selected advanced or recurrent solid tumors with demonstrated high expression of CD166 by IHC.

Part C2 -CX-2009 Monotherapy: Every 14-Day Dosing Regimen
The primary objective of Part C2 is to evaluate the efficacy of CX-2009 when administered IV
every 14 days as monotherapy at the MTD/RP2D to subjects with demonstrated high tumor expression of CD166 by IHC. Efficacy will be assessed on the basis of the ORR by the RECIST Version 1.1.

Part D1 - CX-2009 + CX-072 Combination: Every 14-Day Dosing Regimen
The primary objective of Part D1 is to determine the safety profile, the MTD/RP2D, and the DLTs of
CX-2009 in combination with CX-072, both administered IV every 14 days to subjects with selected
advanced or recurrent solid tumors with demonstrated PD-L1 positivity and high expression of CD166 by
IHC.

Part D2 - CX-2009 + CX-072 Combination: Every 14-Day Dosing Regimen
The primary objective of Part D2 is to evaluate the efficacy of CX-2009 in combination with CX-072,
both administered IV every 14 days at the MTD/RP2D to subjects with demonstrated PD-L1 positivity
and high tumor expression of CD166 by IHC. Efficacy will be assessed on the basis of ORR per RECIST
Version 1.1.

Substudy:
The primary objective of the substudy is to assess the whole body distribution of
Zr-CX-2009, including the uptake (visual and quantitative) in tumor lesions as well as non-tumor tissues, in subjects with unresectable locally advanced or metastatic solid tumors.

Study design

This is a Phase 1-2, open-label, multicenter, dose-finding, and proof of concept study for CX-2009 as monotherapy in subjects with advanced solid tumors in the following indications: breast cancer (BC), castrate-resistant prostate carcinoma, (CRPC), non-small cell lung carcinoma (NSCLC), ovarian epithelial cancer (OEC), endometrial carcinoma (EC), head and neck squamous cell carcinoma (HNSCC), or cholangiocellular carcinoma (CCC). These tumor types have been selected for their known high levels of CD166 expression and sensitivity to microtubule inhibitors. Approximately 563 subjects will be enrolled into the

study.

The study is divided into 7 parts (Parts A, A2, B, C1, C2, D1 and D2), each designed to inform dose selection for the next phase of development. Part A is designed to define the MTD in 2 separate stages: a standard 3+3 escalation followed by a modified toxicity probability interval 2 (mTPI-2) cohort, in patients receiving CX-2009 every 21 days. Part A2 is designed for biomarker evaluation (particularly Probody therapeutic activation) in order to further inform dose optimization. Part B is focused on expanding clinical experience in order to further define the safety profile at the MTD/RP2D as well as to obtain a preliminary assessment of efficacy in a select number of cancers. Part B may be initiated as soon as the MTD/RP2D is defined in Part A and available data from Part A2 are reviewed in consultation with the Safety Review Committee (SRC). Part C1 is designed to define the MTD/RP2D in subjects receiving CX-2009 every 14 days. Part C2 is focused on expanding clinical experience in order to further define the safety profile of CX-2009 and to obtain a preliminary assessment of efficacy when administered every 14 days at the MTD/RP2D. Dose expansion for CX-2009 monotherapy may occur either under the every 21-day dosing regimen (Part B) or the every 14-day dosing regimen (Part C2), depending on available data from Parts A, A2, and C1. Part D1 is designed to define the MTD/RP2D in subjects receiving CX-2009 in combination with CX-072 every 14 days. Part D2 is focused on expanding clinical experience to further define the safety profile of CX-2009 administered in combination with CX-072 and to obtain a preliminary assessment of efficacy of the combination when administered every 14 days at the MTD/RP2D.

Substudy:
The substudy is divided into 2 parts. Up to 3 cohorts of 2 to 3 subjects each will enroll in Part I-1. Subjects in the initial cohort (Cohort 1) will only receive 89Zr-CX-2009 (ie, no unlabeled CX-2009). If Cohorts 2 and 3 are to enroll, subjects will each receive the same fixed dose of Zr-CX-2009 plus an amount of unlabeled CX-2009. Cohort 3 will receive a higher or lower dose of unlabeled CX-2009 than Cohort 2.

Once the optimal dose of unlabeled CX-2009 to be given in combination with Zr-CX-2009 and the optimal timing between 89Zr-CX-2009 administration and 89Zr-CX-2009 PET imaging are determined, Part I-2 will open.

In Part I-2, up to 11 subjects will be enrolled such that the maximum total number of evaluable subjects in Parts I-1 and I-2 will be 20. The optimal dose of unlabeled CX-2009 to be given in combination with 89Zr-CX-2009 will be determined in Part I-1. Subjects in Part I-2 will undergo 89Zr-CX-2009 PET imaging at the optimal 2 time points following Zr-CX-2009 administration as determined in Part I-1.

Intervention

CX-2009 will be supplied as a lyophilized powder (cake) in 25 mg vials to be reconstituted with 5 mL of sterile water for injection (WFI) to a final concentration of 5.0 mg/mL. CX-2009 will be administered as an IV infusion over 90 (±10) minutes with careful monitoring of infusion-related reactions (IRRs).

CX-072 drug product is currently being supplied as a sterile solution for IV administration. CX-072 is supplied in a 10 mL volume, and each vial contains 100 mg of CX-072 formulated with suitable compendial excipients. Upon regulatory approval, the CX-072 drug product is planned to be supplied as a lyophilized powder (cake) in single-use vials for reconstitution with sterile WFI before IV administration. CX-072 is administered at a fixed dose of 800 mg over 60 minutes.

When CX-2009 and CX-072 are administered on the same day, CX-072 is to be administered first, followed by a saline flush, followed by the CX-2009 infusion. CX-2009 is to be infused no sooner than 30 minutes after completion of the CX-072 infusion.

Substudy:
Subjects will be administered 89Zr-CX-2009 via IV once at the start of the substudy, either in combination with unlabeled CX-2009 or without.

Study burden and risks

Risks: possible side effects of the study medication

Burden: study procedures such as blood draws, CT or MRI scans, bonescans and biopsies. A bonescan will only be done with a clinical indication.

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

Subjects who fulfill the following criteria at Screening will be eligible for admission into the
study:
1. Histologically confirmed diagnosis of active metastatic or locally advanced unresectable
solid tumor in subjects who have disease progression after treatment with available therapies
that are known to confer clinical benefit, or who are intolerant to treatment, in the following
indications (with guidance for standard treatment below).
For Parts A2, B, C1, C2, D1, and D2, an archival tumor tissue sample must be submitted to
the central laboratory for evaluation of CD166 expression and demonstrate confirmed high
CD166 expression by IHC. Biopsy collection for the purpose of determining eligibility is not
permitted.
Eligible indications, by Part:
* Part A: BC, CRPC, NSCLC (including adenocarcinoma and squamous cell subtypes), OEC, EC, HNSCC, and CCC;
* Part A2: BC, NSCLC (including adenocarcinoma and squamous cell subtypes), OEC, EC, and HNSCC;
* Parts B, C2, and D2: TNBC, hormone receptor (HR; ie, estrogen and/or progesterone)-positive/HER2-negative BC, NSCLC (including adenocarcinoma and squamous cell subtypes), OEC, and HNSCC; and

* Parts A mTPI-2 cohort, C1, and D1: BC, NSCLC (including adenocarcinoma and squamous cell subtypes), and HNSCC;
Criterion specific to Parts B, C, and D:
* Subjects must have received the standard prior treatments for metastatic or advanced
unresectable disease as outlined below, but not more than 3 (<=3) prior lines in total;
Standard prior treatments, by tumor type:
BC (Parts A, A2, C1, and D1):
* Patients with HER2-positive BC are required to have progressed on HER2-targeted
therapy (trastuzumab, pertuzumab, and/or T-DM1);
* Estrogen-receptor-positive should have received anti-hormonal therapy, a CDK4/6
inhibitor, or mTOR inhibitor and progressed; and
* TNBC should have received at least 2 prior lines of therapy;

TNBC (Parts B, C2, and D2):
* Should have received at least 2 prior lines of therapy; and
* Subjects with BReast CAncer gene (BRCA) mutations must be refractory to or otherwise ineligible for poly adenosine diphosphate-ribose polymerase inhibitors (eg,
olaparib), if approved and available;
HR-positive/HER2-negative BC (Parts B, C2, and D2):
* Should have received and progressed on an anti-hormonal therapy, targeted therapy
(CDK4/6 or mTOR inhibitor), or chemotherapy;
* Endocrine refractory should have received at least 3 prior hormonal therapies and
progressed;
* Post or pre-menopausal subjects receiving ovarian ablation or suppression must have
progressed on an aromatase inhibitor (AI) in combination with a CDK4/6 inhibitor or
fulvestrant in combination with a CDK4/6 inhibitor; and
* Subjects who progressed within 12 months or while on a non-steroidal AI, must have
progressed on an mTOR inhibitor and on a combination of exemestane with everolimus (mTOR);
CRPC (Part A):
* Received at least 1 prior therapy (eg, abiraterone + prednisone, or docetaxel + prednisone, or enzalutamide);
NSCLC, including adenocarcinoma and squamous cell
subtypes (All Parts):
* Should have received at least 1 platinum-containing regimen. as well as an anti-PD-1
or anti-PD-L1 therapy; and an ICI should have been

administered if approved and available for the subject*s indication in their locality
* Subjects harboring genomic aberrations for which FDA-approved targeted therapy is
available (eg, non-resistant epidermal growth factor receptor [EGFR] mutations, EGFR T790M mutation, anaplastic lymphoma kinase (ALK) rearrangement, ROS rearrangement, BRAF V600E mutation) must have received prior treatment with an FDA-approved targeted therapy. Subjects without actionable mutations or rearrangements if progression on all available therapy, including platinum-based combinations, must have received an anti-PD-1/PD-L1 antibody and docetaxel administered with ramucirumab; and
* Subjects with known EGFR tyrosine kinase (TK)-activating mutations or ALK rearrangements must have received a tyrosine kinase inhibitor (TKI);
OEC (Parts A, A2, B, C2, D2):
* Non-BRCA mutation (germline or somatic) subjects or subjects with unknown BRCA mutational status must be platinum-resistant or platinum-refractory ovarian carcinoma for the expansion cohort;
* Subjects with platinum-resistant disease must have progressed on chemotherapy plus
bevacizumab; and
* Subjects with BRCA mutations must be refractory to or otherwise ineligible for poly
adenosine diphosphate ribose polymerase inhibitors (eg, olaparib or rucaparib) if
approved and available;
EC (Parts A, A2):
* Should have received at least 1 platinum-containing regimen for extra-uterine or
advanced disease;
HNSCC (All Parts):
* Must have received a platinum-containing regimen and anti-programmed cell death
protein PD-1 (PD1) if approved and available for subject*s indication in their locality;
and
* Must have progressed on a taxane, cetuximab, or methotrexate;
CCC (Part A):
* Failed at least 1 prior line of a gemcitabine-containing regimen.
Additional Requirements for Parts D1 and D2:
Must have documented evidence of PD-L1-positive tumor status.

2. Agrees to provide tumor tissue; archival, new, or recent acquisition confirmed to be available
prior to initiation of study drug for performance of correlative tissue and cellular studies from
a tumor site not previously irradiated:
* Part A2: subjects must consent to an on-treatment tumor biopsy at 3 to 5 days

after the first dose of CX-2009; and
* Parts B and C2 (monotherapy dose expansions): at least 7 subjects of each tumor type must consent to provide a
pretreatment and on-treatment tumor biopsy and peripheral blood samples 3 to 5 days after the
first dose of CX-2009.

3. Evaluable or measurable disease required for dose escalation (Part A) and measurable disease
per RECIST v1.1 required for Parts A2, B, C1, C2, D1, and D2;
4. Subjects with treated brain metastases are eligible if the brain metastases are stable and the
subject does not require radiation therapy, or steroids. Active screening for brain metastases
(eg, brain computed tomography or magnetic resonance imaging) is not required;
5. At least 18 years of age;
6. Eastern Cooperative Oncology Group performance status of 0 or 1;
7. Anticipated life expectancy of at least 3 months;
8. Screening laboratory values must meet the following criteria:
* Absolute neutrophil count >=1500/uL;
* Platelet count >=100 x 10 ^3 /uL (must not have been transfused within previous
10 days);
* Hemoglobin >=9.0 g/dL (may have been transfused);
* Serum creatinine <=1.5 x institution*s upper limit of normal (ULN);
* Aspartate aminotransferase (AST) <=2.5 x institution*s ULN; alanine aminotransferase
(ALT) <=2.5 x institution*s ULN (AST, ALT <5 x ULN for subjects with CCC and liver metastases);
* Serum total bilirubin <=1.5 x institutional ULN (total bilirubin must be
<=3.0 x institution*s ULN in subjects with Gilbert*s syndrome). Serum total bilirubin
<=3.0 x institutional ULN for subjects with CCC and liver metastasis;
* For Parts B, C, D only:
o Hemoglobin * 9.0 g/dL (without transfusion within 30 days of Cycle 1 Day 1);
o AST, ALT, and alkaline phosphatase (ALP) <=2.5 × institution*s ULN (without exemption for liver or bone metastases);
o International normalized ratio (INR) and activated partial thromboplastin time (aPTT) <=1.5 × ULN (unless subject is on therapeutic anticoagulation, at which time the INR and aPTT must be in the target therapeutic anticoagulation range); and
o Serum albumin >=2.5 g/dL.

9. Women of childbearing potential (defined as women who have experienced menarche and
who are not permanently sterile or postmenopausal; postmenopausal is defined as

12 consecutive months with no menses without an alternative medical cause) and males must
agree to use a highly effective method of contraception prior to study entry, while on study
drug, and for a period of 50 days after the last dose of CX-2009
or 6 months after the last dose of C

Exclusion criteria

Subjects who fulfill any of the following criteria at Screening will not be eligible for admission:

1. Neuropathy >Grade 1;

2. Active or chronic corneal disorder, including but not limited to the following: Sjogren's syndrome, Fuchs corneal dystrophy (requiring treatment), history of corneal transplantation, active herpetic keratitis, and also active ocular conditions requiring ongoing treatment/monitoring such as wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, presence of papilledema, and acquired monocular vision;
3. Serious concurrent illness, including, but not limited to the following:

• Clinically relevant active infection including known active hepatitis B or C, human immunodeficiency virus infection, or cytomegalovirus infection or any other known concurrent infectious disease, requiring IV antibiotic, antiviral, or antifungal therapy within 2 weeks of study enrollment;
• History of or current active autoimmune diseases, including but not limited to myasthenia gravis, inflammatory bowel diseases, rheumatoid arthritis, autoimmune thyroiditis which is not a sequela of prior immune checkpoint therapy, autoimmune hepatitis, systemic sclerosis, systemic lupus erythematosus, autoimmune vasculitis, autoimmune neuropathies, or type 1 insulin dependent diabetes mellitus;
• Significant cardiac disease such as recent myocardial infarction (£6 months prior to
Day 1), unstable angina pectoris, uncontrolled congestive heart failure (New York Heart Association >class II), uncontrolled hypertension (NCI CTCAE v4.03 Grade 3 or higher), uncontrolled cardiac arrhythmias, severe aortic stenosis, or ³Grade 3 cardiac toxicity following prior chemotherapy;
• History of multiple sclerosis or other demyelinating disease, Eaton-Lambert syndrome
(para-neoplastic syndrome), history of hemorrhagic or ischemic stroke within the last
6 months, or alcoholic liver disease;
• Non-healing wound(s) or ulcer(s) except for ulcerative lesions caused by

the underlying neoplasm;
• Psychiatric illness/social situations that would limit compliance with study requirements;
or
• Interstitial lung disease irrespective of etiology;

4. Advanced or metastatic Stage IV NSCLC subjects with EGFR or ALK genomic alterations unless they have progressed on treatment with appropriate targeted therapy, including osimertinib for T790M mutation-positive NSCLC;
5. Any other anticancer treatment such as chemotherapy, immunotherapy, biochemotherapy, radiotherapy, investigative therapy, or high-dose steroids within 30 days of receiving study drug. Low-dose steroids, luteinizing hormone-releasing hormone, aromatase inhibitors
(eg, anastrozole), at doses that have been stable for ³30 days are permitted for subjects with
CRPC;

6. History of severe allergic or anaphylactic reactions to previous mAb therapy;

7. Prior treatment with maytansinoid-containing drug conjugates (eg, Kadcyla [T-DM1]);

8. Subjects with a previously documented absence of thiol-S-purine methyltransferase activity;

9. Unresolved acute toxicity NCI CTCAE v4.03 Grade >1 (or baseline, whichever is greater)
from prior anticancer therapy. Alopecia and other nonacute toxicities are acceptable;

10. History of malignancy that is active within the previous 2 years except for localized cancers that are not related to the current cancer being treated, are considered to have been cured and in the opinion of the Investigator, present a low risk for recurrence, including basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the prostate, cervix or breast;
11. Currently receiving anticoagulation therapy with warfarin;

12. The subject has undergone major surgery (requiring general anesthesia) within 3 months prior to dosing. Subjects who have undergone major surgery within this time period may be enrolled, after consultation with the Medical Monitor;
13. Subjects who have received a live vaccine within 28 days prior to the planned first dose of CX-2009 (examples include, but are not limited to, the following: measles, mumps, rubella, chicken pox/zoster, yellow fever, rabies, Bacillus Calmette-Guérin, and typhoid vaccine);

14. Participating in an ongoing clinical study involving treatment with medications, radiation, or surgery;
15. Women who are pregnant or breast feeding; or

16. Subjects who are >20.0% below their ideal body weight, as determined using the formula in
Appendix F.

Additional Exclusion Criteria for Parts D1 and D2

17. History of myocarditis regardless of the cause;

18. History of intolerance to prior ICI therapy defined as the need to discontinue treatment due to an irAE;
19. History of any syndrome or medical condition that requires treatment with systemic steroids (>=10 mg daily prednisone equivalents) or immunosuppressive medications. However, subjects who require brief courses of steroids (eg, as prophylaxis for IV contrast or for treatment of an allergic reaction) may be eligible with Sponsor approval. Inhaled or topical steroids are permitted;
20. History of allogeneic tissue/solid organ transplant, stem cell transplant, or bone marrow transplant.

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-10-2018
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-CX-2009
Generic name:	-
Product type:	Medicine
Brand name:	CX-072
Generic name:	-
Product type:	Medicine
Brand name:	CX-2009
Generic name:	anti-CD166 antibody

Ethics review

Approved WMO Date:	12-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-12-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2017-000625-12-NL
CCMO	NL61676.029.17

Study results

Date completed:	22-07-2020
Results posted:	08-11-2021
Actual enrolment:	22

Summary results
Trial ended prematurely

First publication

03-09-2021