COVID-19: A Phase 2b/3, Randomized, Observer-Blinded, Placebo-Controlled, Multicenter Clinical Study Evaluating the Efficacy and Safety of Investigational SARS-CoV-2 mRNA Vaccine CVnCoV in Adults 18 Years of Age and Older.

Published: 20-11-2020
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Objectives for the Randomized Observe-Blinded Phase:Primary Objectives:Primary Efficacy Objective• To demonstrate the efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50925

Source
ToetsingOnline

Brief title
HERALD

Condition

- Other condition
- Viral infectious disorders

Synonym
Corona virus, Covid-19

Health condition

SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: CureVac AG
Source(s) of monetary or material Support: Curevac AG

Intervention

Keyword: Covid-19, Phase 2b/3, Vaccine

Outcome measures

Primary outcome

Primary Efficacy Endpoint

• Occurrence of first episodes of virologically-confirmed (RT-PCR positive)

cases of COVID-19 of any severity meeting the case definition for the primary

efficacy analysis.

Primary Safety Endpoints

All safety endpoints will be analyzed in all subjects, in subjects seronegative

at baseline, and in subjects seropositive at baseline.

• Occurrence, intensity, and relationship of medically-attended AEs collected

through 6 months after the second trial vaccination in all subjects.

• Occurrence, intensity, and relationship of SAEs and AESIs collected

throughout the trial in all subjects.

• Occurrence of fatal SAEs throughout the trial in all subjects.

• Occurrence, intensity, and duration of each solicited local AE within 7 days

after each trial vaccination in Phase 2b subjects.

• Occurrence, intensity, duration of each solicited systemic AE within 7 days after each trial vaccination in Phase 2b subjects.

• Occurrence, intensity and relationship of unsolicited AEs occurring within 28 days after each trial vaccination in Phase 2b subjects.

• Occurrence of AEs leading to vaccine withdrawal or trial discontinuation throughout the trial in all subjects.

Secondary outcome

Key Secondary Efficacy Endpoints

• Occurrence of first episodes of virologically-confirmed (RT-PCR positive) cases of moderate to severe COVID-19 meeting the case definition for the primary efficacy analysis (moderate and severe COVID-19 is defined in Appendix 3 and Appendix 4).

• Occurrence of first episodes of virologically-confirmed (RT-PCR positive) severe cases of COVID-19 meeting the case definition for the primary efficacy analysis (severe COVID-19 defined in Appendix 3).

• Occurrence of first episodes of virologically-confirmed (RT-PCR positive) cases of COVID-19 of any severity meeting the case definition due to infection with *wild type* (i.e., WT/D614G lineages A.1/B.1 without VOC B.1.1.7 [Alpha], B.1.351 [Beta], B.1.429 [Epsilon]) and *UK* (B.1.1.7 [Alpha]) SARS CoV 2 strains in SARS CoV 2 naïve subjects.

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Other Secondary Efficacy Endpoints

• In subjects >= 61 years of age, occurrence of first episodes of virologically

confirmed (RT-PCR positive) cases of COVID-19 of any severity meeting the case definition for the primary efficacy analysis.

• Occurrence of virologically-confirmed (RT-PCR positive) SARS CoV 2 infection, with or without symptoms.

If subject was symptomatic, onset of symptoms must have occurred >= 15 days following the second trial vaccination; if subject was asymptomatic, the positive RT-PCR test must have occurred >= 15 days following the second trial vaccination.

• BoD scores calculated based on first episodes of virologically confirmed (RT-PCR positive) cases of COVID-19 of any severity meeting the case definition for the primary efficacy analysis.

o BoD #1 - no disease (not infected or asymptomatic infection) = 0; mild or moderate disease = 1; severe disease = 2.

o BoD #2 - no disease (not infected or asymptomatic infection) = 0; disease without hospitalization = 1; disease with hospitalization = 2; death = 3.

• Occurrence of first episodes of virologically-confirmed (RT-PCR positive) cases of COVID-19 of any severity with symptom onset at any time after the first trial vaccination.

Secondary Immunogenicity Endpoints (Phase 2b Immunogenicity Subset)

SARS-CoV-2 RBD of S protein antibody responses

On Days 1, 29, 43, 120, and 211:

• Serum antibodies to SARS-CoV-2 RBD of S protein.

• Occurrence of seroconversion to SARS-CoV-2 RBD of S protein.

Seroconversion is defined as detectable SARS-CoV-2 RBD of S protein antibodies

in the serum of subjects who tested seronegative at baseline.

SARS-CoV-2 viral neutralizing antibody responses

On Days 1, 29, 43, 120, and 211:

• Serum neutralizing antibodies to SARS-CoV-2 virus, as measured by a viral neutralizing antibody assay.

• Occurrence of seroconversion to SARS-CoV-2 virus, as measured by a viral neutralizing antibody assay.

Seroconversion is defined as detectable SARS-CoV-2 viral neutralizing antibodies in the serum of subjects who tested seronegative at baseline.

Study description

Background summary

Coronaviruses are a large family of zoonotic ribonucleic acid (RNA) viruses causing respiratory disease, ranging from a common cold to severe diseases such as Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS) in humans. In December 2019, an outbreak of respiratory disease caused by a novel coronavirus strain was reported in Wuhan City, Hubei Province, China. The novel coronavirus was named *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2), while the disease associated with it was referred to as COVID-19 (coronavirus disease 2019). The virus spread to different parts of China and an increasing number of countries worldwide and on 30 January 2020 the World Health Organization (WHO) announced the outbreak under International Health Regulations as a public health emergency of international concern (the WHO's highest level of alarm). On 12 March 2020, the WHO announced the outbreak as a pandemic.

In view of the severity of respiratory disease caused by emerging coronaviruses, development of a vaccine has been undertaken by several pharmaceutical companies, and there are now vaccines available with emergency authorization/conditional marketing authorization for prevention of COVID 19 in several countries worldwide. CureVac AG is developing a novel SARS-CoV-2 vaccine referred to as CVnCoV. CVnCoV is a messenger RNA (mRNA) based COVID-19 vaccine in which the mRNA is protected and delivered by encapsulation within lipid nanoparticles (LNPs). The mRNA encodes the stabilized full-length spike

(S) protein from the SARS-CoV-2 virus. Following intramuscular (IM) injection of CVnCoV, the S protein is translated from the mRNA stimulating an antigen specific humoral and cellular immune response to the S protein. Importantly, functional viral neutralizing titers (VNTs) are induced following vaccination with CVnCoV.

Phase 1 and 2a trials are being conducted to generate initial data on the safety, reactogenicity, and immunogenicity of 2 doses of CVnCoV, administered 28 days apart, to adults 18 years of age and older. In a subset of subjects, a booster dose at 2 or 6 months after the first dose will be investigated. The first-in-human (FIH) Phase 1 trial, CV-NCOV-001, is evaluating different dose levels of CVnCoV in seronegative and seropositive adults 18 to 60 years of age. Following review of the FIH data, a Phase 2a trial, CV-NCOV-002, was initiated and is evaluating CVnCoV at selected dose levels in adults >= 61 years of age. Following the first part of Trial CV NCOV 002, expansion cohorts of 220 subjects aged 18 to 60 years and 220 subjects aged >= 61 years are being enrolled and treated to generate additional safety and immunogenicity data in preparation of Phase 2b/3 trials. Dose level selection for subsequent trials will be performed based on the safety and immunogenicity data from these 2 trials. In the FIH Phase 1 trial, a dose of 12 µg elicited the same immune response as that seen in patients who are recovering from having been infected with the real virus. Therefore, this dose was selected to be used in this trial.

The present trial CV-NCOV-004 is designed as a Phase 2b/3 pivotal efficacy and safety trial in adults 18 years of age and older. The trial will have a randomized, observer-blinded, placebo-controlled design. Subjects will be enrolled at multiple sites globally and will be randomized in a 1:1 ratio to receive a 2-dose schedule of either CVnCoV at a dose level of 12 µg mRNA or placebo {normal saline (0.9% NaCl)} as the control.

The above described randomized, observer-blinded phase will be followed by an open label phase. The open-label phase has been added to inform all subjects about the trial treatment they received and to allow follow-up of subjects who received at least 1 dose of CVnCoV, including those who decide(d) after unblinding to receive an authorized/licensed vaccine for preventing COVID-19 (AV) through their national vaccination program. Placebo subjects do not require further follow-up and will discontinue the trial.

Study objective

Objectives for the Randomized Observe-Blinded Phase:

Primary Objectives:
Primary Efficacy Objective
• To demonstrate the efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity in SARS-CoV-2 naïve subjects.

Primary Safety Objectives
• To evaluate the safety of CVnCoV administered as a 2-dose schedule to subjects 18 years of age and older.
• To evaluate the reactogenicity of CVnCoV administered as a 2-dose schedule to subjects 18 years of age and older participating in Phase 2b of the trial.

Secondary Objectives:
Key Secondary Efficacy Objectives
• To demonstrate the efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed moderate to severe cases of COVID-19 in SARS-CoV-2 naïve subjects.
• To demonstrate the efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed severe cases of COVID-19 in SARS-CoV-2 naïve subjects.
• To demonstrate the efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity caused by *wild type* (i.e., WT/D614G lineages A.1/B.1 without the variant of concern [VOC] B.1.1.7 [Alpha], B.1.351 [Beta], B.1.429 [Epsilon]) and *UK* (B. 1.1.7 [Alpha]) SARS CoV 2 strains in SARS CoV 2 naïve subjects.
Other Secondary Efficacy Objectives
To evaluate in SARS-CoV-2 naïve subjects:
• The efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity in subjects >= 61 years of age.
• The efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of SARS-CoV-2 infection, with or without symptoms.
• The efficacy of a 2-dose schedule of CVnCoV in reducing the Burden of disease (BoD) from COVID-19.
• The efficacy of CVnCoV after the first dose in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity.
Secondary Immunogenicity Objectives
• To assess antibody responses to the receptor binding domain (RBD) of S protein of SARS-CoV-2 after 1 and 2 doses of CVnCoV in a subset of subjects participating in Phase 2b of the trial.
• To assess SARS-CoV-2 viral neutralizing antibody responses after 1 and 2 doses of CVnCoV in a subset of subjects participating in Phase 2b of the trial.

Exploratory Efficacy Objectives
To investigate in SARS-CoV-2 naïve subjects:
• The efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity caused by individual VOCs (see Section 9.2.1.6).
• If cases of COVID-19 are milder in severity in subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• If the need for supplemental oxygenation due to COVID-19 is reduced in

subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• If the need for mechanical ventilation due to COVID-19 is reduced in subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• If hospitalization due to COVID-19 is reduced in subjects receiving a 2 dose schedule of CVnCoV compared to those administered placebo.
• If mortality due to COVID-19 is reduced in subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• If all-cause mortality is reduced in subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• To investigate the cell-mediated immune response of a 2-dose schedule of CVnCoV from approximately 200 subjects at selected site(s).
To investigate in SARS-CoV-2 naïve and non-naïve subjects:
• The efficacy of a 2-dose schedule of CVnCoV in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity in all subjects, regardless of SARS-CoV-2 serological status at baseline.
• The efficacy of CVnCoV after the first dose in the prevention of first episodes of virologically-confirmed cases of COVID-19 of any severity in all subjects, regardless of SARS-CoV-2 serological status at baseline.
To investigate in subjects with first episodes of virologically confirmed COVID-19 during the trial:
• The occurrence of second episodes of COVID-19 in subjects receiving a 2-dose schedule of CVnCoV compared to those administered placebo.
• To explore correlates of protective immunity induced by CVnCoV vaccination.

Objectives for the Open-label Phase:
• To evaluate safety in all subjects >= 18 years of age remaining in the trial after unblinding.

Open-label Exploratory Objective:
• To describe the number of first episodes of symptomatic virologically confirmed cases of mild, moderate, and severe COVID-19 as assessed by the Investigator.

Study design

Trial CV-NCOV-004 will start with an initial Phase 2b part followed by a large Phase 3 efficacy part. Both Phase 2b and Phase 3 parts will be randomized, observer-blinded, and placebo controlled. Adult subjects 18 years of age or older will be enrolled at multiple sites globally and will receive a 2-dose schedule of either CVnCoV at a dose level of 12 µg mRNA or placebo {normal saline (0.9% NaCl)} in a 1:1 ratio. Both Phase 2b and Phase 3 parts of the trial are consistent in design (e.g., for COVID-19 case ascertainment and case definition) so that cases of COVID-19 occurring in Phase 2b can be pooled with those in Phase 3 for the primary analysis of vaccine efficacy (VE).

For subjects participating in Phase 2b Immunogenicity Subset (see Table 1):
o 7 protocol-scheduled site visits on Day 1, Day 29, Day 43, Day 57, Day 120, Day 211, and Day 393.
o 3 protocol-scheduled phone contacts (safety calls) on Day 2, Day 30 and Day 302.

For subjects participating in Phase 2b non-immunogenicity (see Table 2):
o 6 protocol-scheduled site visits on Day 1, Day 29, Day 43, Day 120, Day 211, and Day 393.
o 4 protocol-scheduled phone contacts (safety calls) on Day 2, Day 30, Day 57, and Day 302.

For subjects participating in Phase 3 (see Table 3):
o 5 protocol-scheduled site visits on Day 1, Day 29, Day 43, Day 211 and Day 393.
o 3 protocol-scheduled phone contacts (safety calls) on Day 57, Day 120 and Day 302.

This randomized observer-blinded phase will be followed by a Phase 3 open label phase. The trial will be unblinded on country/site level after receipt of Competent Authority/Ethics Committee approval of Protocol version 4.0.

Subjects of the placebo treatment arm will be notified of the trial treatment they received by a Subject Information Letter and will be withdrawn after an EOT phone call. Subjects of the CVnCoV treatment arm will be notified of the trial treatment they received at the next planned trial visit/phone call.

For subjects participating in the Open-label Phase:
Cohort A: CVnCoV-AV (Table 4) and Cohort B: CVnCoV only (Table 5):
o Phone calls or clinic visits will be performed after trial unblinding on Day 302 and Day 393/EOT of the original Phase 2b/3 schedule.

Cohort A: CVnCoV-AV (See Table 4 for the Schedule of Trial Assessments and Procedures): Subjects >= 18 years who received at least 1 dose of CVnCoV and choose to receive an AV are included in this cohort and will be recommended to procure AV as standard of care per their national vaccination program, if not already done. Subjects will be requested to remain in the trial for safety follow up until the EOT (Day 393 of the original Phase 2b/3 schedule). Subjects who were individually unblinded and already received an AV before implementation of Protocol version 4.0 will also be included in this cohort.

Cohort B: CVnCoV only (See Table 5 for the Schedule of Trial Assessments and Procedures): Subjects >= 18 years who received at least 1 dose of CVnCoV and choose to remain in the trial without receiving any AV will continue follow up until EOT (Day 393 of the original Phase 2b/3 schedule). Subjects who were individually unblinded during the randomized observer-blinded phase and who received CVnCoV but did not receive an AV before implementation of Protocol

version 4.0 and do not intend to receive an AV will also be included in this cohort. Subjects who initially intend to complete the trial without receiving an AV and later decide to receive an AV within the open-label phase will be switched to Cohort A.
Placebo subjects do not require further follow up and will discontinue the trial.
The open-label phase will provide additional safety data, including data from subjects who receive an AV after CVnCoV. COVID-19 cases will continue to be documented, but there will no longer be any inferential efficacy analysis in the open-label phase (only descriptive summary of cases). Subjects will undergo passive surveillance for COVID-19.

Intervention

2 doses of CvnCoV (12 µg dose) or saline placebo, 28 days apart, administered via intermuscular injection

Study burden and risks

We do not know all the possible side effects of CVnCoV. Like all vaccines, CVnCOV can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some people may experience serious side effects and may require treatment.
This CVnCoV vaccine is currently being assessed in humans in a parallel study. The final data are not yet available, but so far, no safety concerns have been reported. Some participants experienced reactions that kept them from doing their routine daily activity during one or maximum two days* in most cases. Other side effects that may occur: Allergic reactions, immune response, reaction to the blood collection or nose swab.

For a more detailed overview of the potential side effects please consult the Protocol, Investigator's Brochure and Informed Consent Form provided with this inititial submission.

Contacts

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CureVac AG

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for all subjects:
Subjects will be enrolled in this trial only if they meet all of the following criteria:
1. Male or female subjects 18 years of age or older.
2. Be willing and able to provide written informed consent prior to initiation of any trial procedures..
3. Expected compliance with protocol procedures and availability for clinical follow-up through the last planned visit.
4. Females of non-childbearing potential defined as follows: surgically sterile (history of bilateral tubal ligation/occlusion, bilateral oophorectomy or hysterectomy) or postmenopausal {defined as amenorrhea for >= 12 consecutive months prior to screening (Day 1)} without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the Investigator to confirm postmenopausal status.
5. Females of childbearing potential: negative pregnancy test {human chorionic gonadotropin (hCG)} within 24 hours prior to each trial vaccination on Day 1 and Day 29.
6. Females of childbearing potential must use highly effective methods of birth control from 2 weeks before the first administration of the trial vaccine until 3 months following the last administration. The following methods of birth control are considered highly effective when used consistently and correctly:
• Combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal);
• Progestogen-only hormonal contraception associated with inhibition of

ovulation (oral, injectable or implantable);
• Intrauterine devices;
• Intrauterine hormone-releasing systems;
• Bilateral tubal ligation;
• Vasectomized or infertile partner;
7. Sexual abstinence {periodic abstinence (e.g., calendar, ovulation, symptothermal and post-ovulation methods) and withdrawal are not acceptable}.

Exclusion criteria

Subjects will not be enrolled in this trial if they meet any of the following criteria:
1. History of virologically-confirmed COVID-19 illness.
2. For females: pregnancy or lactation.
3. Use of any investigational or non-registered product (vaccine or drug) within 28 days preceding the administration of the first trial vaccine or planned use during the trial.
4. Receipt of licensed vaccines within 28 days (for live vaccines) or 14 days (for inactivated or any other vaccines) prior to the administration of the first trial vaccine.
5. Prior administration of any investigational SARS-CoV-2 vaccine or another coronavirus (SARS-CoV, MERS-CoV) vaccine or planned use during the trial.
6. Any treatment with immunosuppressants or other immune-modifying drugs (including but not limited to anabolic steroids, corticosteroids, biologicals and methotrexate) for > 14 days total within 6 months preceding the administration of trial vaccine or planned use during the trial. For corticosteroid use, this means prednisone or equivalent, 0.5 mg/kg/day for 14 days or more. The use of inhaled, topical, or localized injections of corticosteroids (e.g., for joint pain/inflammation) is permitted.
7. Any medically diagnosed or suspected immunosuppressive or immunodeficient condition based on medical history and physical examination including known infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV); current diagnosis of or treatment for cancer including leukemia, lymphoma, Hodgkin disease, multiple myeloma, or generalized malignancy; chronic renal failure or nephrotic syndrome; and receipt of an organ or bone marrow transplant.
8. History of angioedema (hereditary or idiopathic) or history of any anaphylactic reaction.
9. History of pIMD.
10. History of allergy to any component of CVnCoV vaccine.
11. Administration of immunoglobulins or any blood products within 3 months prior to the administration of trial vaccine or planned receipt during the trial.
12. Subjects with a significant acute or chronic medical or psychiatric illness that, in the opinion of the Investigator, precludes trial participation (e.g.,

may increase the risk of trial participation, render the subject unable to meet the requirements of the trial, or may interfere with the subject*s trial evaluations). These include severe and/or uncontrolled cardiovascular disease, gastrointestinal disease, liver disease, renal disease, respiratory disease, endocrine disorder, and neurological and psychiatric illnesses. However, those with controlled and stable cases can be included in the trial.
13. Subjects with impaired coagulation or any bleeding disorder in whom an IM injection or a blood draw is contraindicated.
14. Foreseeable non-compliance with the trial procedures as judged by the Investigator.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2020
Enrollment:	2400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CVnCoV

Ethics review

Approved WMO Date:	20-11-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-12-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-01-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-01-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	12-03-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-04-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	09-04-2021
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)
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Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-01-2022
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	EUCTR2020-003998-22-NL
CCMO	NL75450.000.20