First-in-human trial of the Coronavirus virus-like particle subunit vaccine ABNCoV2 in SARS-CoV-2-naïve adult volunteers in good health (COUGH-1)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50898

Source
ToetsingOnline

Brief title
Safety and tolerability of ABNCoV2

Condition

- Other condition
- Viral infectious disorders
- Respiratory tract infections

Synonym
coronavirus, COVID-19

Health condition

COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: COVID-19, SARS-CoV2, Vaccine

Outcome measures

Primary outcome

Clinical Trial Protocol section 10.1

- Number of at least possibly related Grade 3 adverse events (AE) and serious adverse events (SAE) from time of first administration of ABNCoV2 to the end of the follow-up period.

- Concentration of ABNCoV2-specific antibodies 14 days following first vaccination.

Secondary outcome

Clinical Trial Protocol section 10.2

- Number and severity of at least possibly related solicited AEs within one week following administration of ABNCoV2 (day 0 to 7).

Exploratory study endpoints (Clinical Trial Protocol section 10.3):

- Concentration of ABNCoV2-specific antibodies at baseline and during immunization and follow up.

- Inhibitory titre in invasion inhibition assay at baseline and during immunization and follow up.

- Cellular immune responses (T and B cell) at baseline and during immunization

and follow up.

Study description

Background summary

Clinical Trial Protocol section 1.1
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a zoonotic virus, primarily causing respiratory symptoms in humans, ranging from very mild to life threatening. The current outbreak of SARS-CoV-2 was first reported in late 2019 and has spread rapidly around the world, leading the World Health Organization (WHO) to declare a pandemic. A vaccine could complement non-pharmaceutical interventions (NPC), in order to protect vulnerable populations by reducing virus-spread, decrease the load on health care systems and reduce the economic impact of NPC. The ABNCoV2 vaccine is intended to protect against coronavirus disease 2019 (COVID-19) and limit spread of SARS-CoV-2.

Study objective

Clinical Trial Protocol section 2.
The main objectives of the trial are to assess the safety and tolerability of two doses of ABNCoV2, formulated with and without the adjuvant MF59, in healthy adult volunteers and to identify the dosage and formulation that optimizes the immunogenicity-tolerability ratio 14 days following first vaccination with ABNCoV2.

Study design

Clinical Trial Protocol section 3.
This first-in-human phase 1 trial of ABNCoV2 is a single center, sequential dose-escalation, open labelled trial to establish the safety and tolerability of two doses of ABNCoV2, formulated with and without MF59 in healthy, adult, SARS-CoV-2-naïve volunteers. The trial will be carried out by the Radboud University Medical Center (Radboudumc).
Seven groups of volunteers (n=6) will receive a given dose of ABNCoV2, either with or without the adjuvant MF59, followed by a booster with the same dose and formulation four weeks after the first vaccination. All vaccinations will be given as intramuscular injection. The pre-defined escalation schedule will start with 6 *g ABNCoV2, followed by 12, 25 and 50 µg with a maximum dose of 70 µg. MF59-adjuvanted and non-adjuvanted formulations will be tested in parallel until superiority or futility of the MF59-adjuvanted against the non-adjuvanted

formulation is shown. Follow-up visites will take place at the following timepoints: day 1, 7, 14, 25, 29, 35, 42, 70, 119 and 196 after the first ABN-CoV2 administration. Follow-up visits by telephone will occur 2 days after the ABN-CoV2 vaccine and booster administration. All subjects will be followed for approcimately 196 days (28 weeks) after the first ABN-CoV2 vaccine administration.

Intervention

Clinical Trial Protocol section 5.
Volunteers will sequentially receive an administration of non-adjuvanted or MF59-adjuvanted ABNCoV2 vaccination. All subjects will receive a booster with the same dose and formulation 4 weeks following the first vaccination.

Study burden and risks

There is no direct benefit from participation in this trial. Information about their own general health status may be a potential indirect benefit for participants. It will be made clear that the vaccine is experimental and may not protect against COVID-19. Participating in this trial includes risks associated with intramuscular ABNCoV2 administration, immune-response against the vaccine and blood sampling. Volunteers will experience frequent follow-up visits, physical examinations, screening for HIV, hepatitis B and hepatitis C, drug screening, a pregnancy test (for females) and COVID-19 diagnostics. They are expected to fill out a memory aid/diary, measure their temperature during one week following ABNCoV2 administrations and abiding to all the study rules.

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. Subject must sign written informed consent to participate in the trial.
2. Subject is able to understand planned study procedures and demonstrate comprehension of the protocol procedures and knowledge of the study by passing a quiz (assessment of understanding). Subjects must score at least 80% correct on a multiple-choice quiz. If they do not score 80% on the initial quiz, the protocol information will be reviewed with them, and they will have the opportunity to retest.
3. In the opinion of the investigator, the subject can and will comply with the requirements of the protocol.
4. Subjects are available to attend all study visits and are reachable by phone throughout the entire study period from day -1 until 24 weeks following last vaccination (end of study).
5. Subject is a male or non-pregnant and non-lactating female age * 18 and * 55 years and in good health at time of ABNCoV2 administration.
6. Subject agrees to their general practitioner (GP) being informed about participation in the study and agrees to sign a form to request the release by their GP, and medical specialist when necessary, of any relevant medical information concerning possible contra-indications for participation in the study to the investigator(s).
7. The subject agrees to refrain from blood donation to Sanquin or for other purposes throughout the study period according to current Sanquin guidelines.
8. Female subjects of non-childbearing potential may be enrolled in the study. Non-childbearing potential is defined as pre-menarche, current bilateral tubal ligation or occlusion, hysterectomy, bilateral ovariectomy or post-menopause. All other female subjects must agree to use continuous adequate contraception for the duration of the study. Female subjects must have a negative pregnancy test at the inclusion visit.

Exclusion criteria

1. Any clinically significant abnormal finding on clinical examination or laboratory screening tests according to the FDA Toxicity Grading Scale for Healthy Adult and Adolescent Subjects Enrolled in Preventative Vaccine Clinical Trials.
2. History of COVID-19 infection.
3. Chronic use of immunosuppressive drugs or other immune modifying drugs within six months prior to study onset (inhaled and topical corticosteroids and oral anti-histamines exempted) or expected use of such during the study period.
4. Positive urine toxicology test for cannabis, cocaine or amphetamines at inclusion.
5. Screening tests positive for SARS-CoV-2, SARS-CoV-2 antibodies, Human Immunodeficiency Virus (HIV), active Hepatitis B Virus (HBV), or Hepatitis C Virus (HCV).
6. Receipt of any investigational or non-registered product (drug or vaccine) other than the study product in the 30 days preceding enrolment or during the study period.
7. Participation in any other clinical study in the 30 days prior to the start of the study or during the study period.
8. Immunization with any vaccines within the past four weeks or planned receipt of a vaccine during the study period with the exception of a licensed SARS-CoV-2 vaccine, given within the framework of the national SARS-CoV-2 vaccination campaign. The time between last vaccination with ABNCoV2 and a SARS-CoV-2 vaccine provided by the campaign shall be at least 4 weeks.
9. Known hypersensitivity to any of the vaccine components (adjuvant or protein).
10. Administration of immunoglobulins and/or any blood products within the three months prior to the first dose of ABNCoV2 or planned administration during the study period.
11. Previous participation in a COVID-19 vaccine study.
12. Body Mass Index (BMI) >35 kg/m2.
13. Pregnancy, lactation or intention to become pregnant during the study period.
14. History of drug or alcohol abuse interfering with normal functioning in the five years preceding enrolment.
15. Being an employee or student of the department of Medical Microbiology of the Radboudumc, or a person otherwise related to the investigator other than a professional relationship for clinical trial purpose only.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2021
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ABN-COV2 vaccine

Ethics review

Approved WMO Date:	12-01-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-03-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-03-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	26-03-2021

Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-07-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	10-11-2021
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

ID: 20987
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-004621-22-NL
CCMO	NL76192.000.20
OMON	NL-OMON20987

Study results

Date completed:	07-03-2022
Actual enrolment:	45