Safety and tolerability of ABNCoV2

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20987

Source
NTR

Brief title
COUGH-1

Health condition

SARS-CoV-2, COVID-19

Sponsors and support

Primary sponsor: Stichting Radboud universitair medisch centrum
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

Primary safety endpoint: Number of at least possibly related Grade 3 adverse events (AE) and serious adverse events (SAE) from time of first administration of ABNCoV2 until the end of the follow-up period.
Primary immunogenicity endpoint: Concentration of ABNCoV2-specific antibodies 14 days following first vaccination.

Secondary outcome

Number and severity of at least possibly related solicited AEs within one week following administration of ABNCoV2.

Study description

Background summary

Rationale: 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 social and economic impact of NPC. The ABNCoV2 vaccine is intended to protect against coronavirus disease 2019 (COVID-19) and limit spread of SARS-CoV-2.

Objective: 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: COUGH-1 is a phase 1, single centre, open labelled trial in healthy, adult, SARS-CoV-2-naïve volunteers. The trial involves first-in-human administration, pre-defined, sequential dose escalation of ABNCoV2, and adjuvant selection. It intends to inform dosage and formulation for subsequent clinical development.

Study population: Healthy, SARS-CoV-2-naïve, adult female and male volunteers, 18-55 years old.

Intervention: ABNCoV2 is a virus-like particle vaccine. It will be administered as two intramuscular injections in groups of up to 9 volunteers. The pre-defined escalation schedule will start with 6 µg 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 to detect superiority or futility of the MF59-adjuvanted against the non-adjuvanted formulation at the 6, 12 and 25 µg dosage. Approval for further dose escalation and choice of adjuvant use will be provided by a safety monitoring committee (SMC), supported by pre-defined analyses of safety, tolerability and immunogenicity data at day 14 post-first-vaccination. Recruitment for the two best (safe, tolerable and most immunogenic) regimens will continue until 12 volunteers per regimen have been immunized.

Main study parameters/endpoints: Safety – number of at least possibly related Grade 3 adverse events (AE) and serious adverse events (SAE) from time of first administration of ABNCoV2 until the end of the follow-up period and number and severity of at least possibly related solicited AEs within one week following administration of ABNCoV2. Immunogenicity –

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

Study objective

Two doses of the Coronavirus virus-like particle subunit vaccine ABNCoV2 in SARS-CoV-2-naïve healthy adults is safe and well tolerated.

Study design

D-3, D0, D1, D2, D7, D14, D25, D28, D29, D30, D35, D42, D70, D119, D196

Intervention

The trial involves first-in-human administration, pre-defined, sequential dose escalation of ABNCoV2, and adjuvant selection.

Contacts

Public
Radboud university medical center
Merel Smit

024-3619515
Scientific
Radboud university medical center
Merel Smit

024-3619515

Eligibility criteria

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 contraception2 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 US Food and Drug Administration (FDA) Toxicity Grading Scale for Healthy Adult and Adolescent Subjects Enrolled in Preventative Vaccine Clinical Trials [30].
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.
16. Any other condition or situation that would, in the opinion of the investigator, place the subject at an unacceptable risk of injury or render the subject unable to meet the requirements of the protocol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2021
Enrollment:	45
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50898
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9334
CCMO	NL76192.000.20
OMON	NL-OMON50898

Study results