A phase 1 single ascending dose study in healthy subjects to evaluate safety, tolerability, and pharmacokinetics of XVR011

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Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49939

Source
ToetsingOnline

Brief title
Single ascending dose (SAD) study with XVR011 in healthy subjects

Condition

- Viral infectious disorders

Synonym
COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: ExeVir Bio BV

Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Pharmacokinetics, SAD, Safety, XVR011

Outcome measures

Primary outcome

To evaluate the safety and tolerability of XVR011 after an intravenous (iv)

infusion of single ascending doses in healthy subjects.

Secondary outcome

To evaluate the pharmacokinetic (PK) profile of XVR001 after an iv infusion of

single ascending doses in healthy subjects

(Exploratory: To evaluate the immunogenicity of XVR011 after an iv infusion of

single ascending doses in healthy subjects.)

Study description

Background summary

XVR011 is a new compound that may potentially be used for the treatment of COVID 19, the disease that is caused by the coronavirus (officially SARS CoV 2). When the term *coronavirus* is used in this document, it refers to SARS CoV 2. COVID-19 is an infectious disease that causes respiratory tract infections and is spread worldwide. Most people with COVID-19 will experience mild to moderate respiratory illness and recover without requiring special treatment. Some people may have more serious disease such as the *acute respiratory distress syndrome* (a sudden inflammatory response in the lungs) or other major organ dysfunctions that requires staying in the hospital.

XVR011 is what is called a biological compound, which means that the active ingredient is made by a living organism, such as bacteria, fungi, animal or human cells. XVR011 is a type of protein. It has been shown in preclinical studies to specifically bind to the virus and hereby neutralizes the virus, and thus prevents the virus from entering the cells in your body where it would

multiply.

Study objective

In this study, we will investigate how safe the new compound XVR011 is and how well it is tolerated when it is used by healthy participants.

We will also investigate how quickly and to what extent XVR011 is absorbed, transported, and eliminated from the body.

We will compare the effects of XVR011 with the effects of a placebo.

XVR011 has been extensively tested in the laboratory and on animals. It has not yet been used by humans before.

Study design

The study will take a maximum of 15 weeks from the screening until the follow-up visit.

1 short visit for screening, stay in the research for 1 period of 3 days (2 nights). Followed by 6 short visits on Days 8, 15, 29, 43, 59 and the follow-up visit on Day 85. Day 1 is the day when subjects receive the study compound.

Screening -> Day -21 up to Day -1
Entry -> Day -1
In-house stay -> Day -1 up to Day 2
Departure -> Day 2
Short visits -> Day 8, 15, 29, 43 and 57
Follow-up -> Day 85

Subjects will receive XVR011 or placebo as an intravenous infusion. They will have to stay in bed for 2 hours after the infusion. Whether they will receive XVR011 or placebo will be determined by chance. Per group, 8 participants will receive XVR011 and 2 participants will receive placebo.

Intervention

In the table below are the planned treatments for this study. The doses of Groups 2 and 3 may be adjusted. For example because XVR011 had more or less effect than was expected. However, the dose will not be higher than 1000 mg. The XVR011 dose for the next group will only be increased if the lower dose of the previous group was found to be well tolerated and in case of no objection by the Medical Research Ethics Committee. The study will be discontinued or the dose will be decreased if, in the opinion of the investigators, unacceptable side effects appear. The study will also be stopped if unacceptable side

effects appear in the patient study that will run at the same time as this study.

The planned treatments for the study are as follows:

Group | Number of participants per treatment | Dose* of XVR011 | How often

1 | 8 participants will receive XVR011 | 250 mg | Once
1 | 2 participants will receive placebo | - | Once

2 | 8 participants will receive XVR011 | 500 mg | Once
2 | 2 participants will receive placebo | - | Once

3 | 8 participants will receive XVR011 | 1000 mg | Once
3 | 2 participants will receive placebo | - | Once

*In case the dose level will be lower or higher than planned, then we will tell the subjects.

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. On the day of administration of the study compound, blood will be sampled very frequently using an indwelling cannula to determine the course of the concentration of XVR011 in the blood over time. The use of the indwelling canula can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and/or bruising around the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, seating, low heart rate, or a drop in blood pressure with dizziness or fainting.

In total, we will take about 150 mL of blood. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn will be more than 150 mL.

Heart tracing
To make a heart tracing, electrodes will be placed on arms, chest, and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Fasting
If subjects have to fast for a prolonged time during the study, this may lead to symptoms such as dizziness, headache, stomach upset, or fainting.

Coronavirus test
Samples for the coronavirus test will be taken from the back of the nose and

throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause subjects to gag. When the sample is taken from the back of the nose, they may experience a stinging sensation and the eyes may become watery.

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. Sex: male or female; females may be of childbearing potential or of nonchildbearing potential (ie, surgically sterilized, physiologically incapable of becoming pregnant, or at least 1 year postmenopausal [amenorrhea duration of 12 consecutive months and confirmed by a serum follicle stimulating hormone (FSH) test at screening]).

2. Age: 18 to 65 years, inclusive, at screening.
3. Body mass index (BMI): 18.0 to 30.0 kg/m2, inclusive, at screening.
4. Weight : >=50 kg.
5. In good physical and mental health on the basis of medical history, physical examination, clinical laboratory, ECG, and vital signs, as judged by the Investigator.
6. Subject is fully vaccinated against COVID-19 at least 14 days prior to study drug administration, or has had COVID-19 previously and is willing to delay any potential further planned vaccination until 90 days after study drug administration, or is not planning any vaccination until 90 days after study drug administration for reasons other than participation in this study.
Previous COVID infection must not have been within 2 months prior to the date of screening.

Exclusion criteria

1. Previous participation in the current study.
2. Employee of PRA or the Sponsor.
3. History of relevant drug allergies (eg, allergy or hypersensitivity reaction to any monoclonal antibody or to any components of the study drug) and/or food allergies.
4. Using tobacco products within 60 days prior to study drug administration.
5. History of alcohol abuse or drug addiction within 12 months prior to the screening visit (including soft drugs like cannabis products).
6. Positive drug and alcohol screen (opiates, methadone, cocaine, amphetamines [including ecstasy], cannabinoids, barbiturates, benzodiazepines, gamma hydroxybutyric acid, tricyclic antidepressants, and alcohol) at screening or admission to the clinical research center.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-08-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-08-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2021-003707-17-NL
CCMO	NL78439.056.21

Study results

Date completed:	17-01-2022
Results posted:	05-10-2022

First publication
20-05-2022