A Phase I, Randomized, Double-Blind, Placebo-Controlled, Dose Escalation Study To Assess The Safety, Tolerability, Pharmacokinetics Of Two Monoclonal Antibodies In Healthy Volunteers

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In this study we will investigate how safe the experimental compounds AER001 and AER002 are and how well they are tolerated when they are used in healthy subjects.We also investigate how quickly and to what extent AER002 (as a single dose) and...

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

Summary

ID

NL-OMON51340

Source
ToetsingOnline

Brief title
Safety, tolerability and PK of Two Monoclonal Antibodies

Condition

- Viral infectious disorders

Synonym
COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Aerium Therapeutics
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Antibody, Monoclonal, PK, Safety

Outcome measures

Primary outcome

To evaluate the safety and tolerability of AER001 and AER002 in healthy

volunteers

Secondary outcome

- To assess the pharmacokinetics and pharmacodynamics of AER001 and AER002

- To assess the immunogenicity of AER001 and AER002

Exploratory objective

- To assess the proportion of COVID-19 infections after Day 1.

- To assess the penetration of AER001 and AER002 in the upper airway

Study description

Background summary

AER001 and AER002 are experimental compounds that may potentially be used for the preventative treatment of coronavirus disease 2019 (COVID-19). AER001 and AER002 are human antibodies that bind to the SARS-CoV 2 virus (coronavirus) in a way that prevents it from entering human cells. Research has shown that the combination of these antibodies can bind to all dominant coronavirus variants. These antibodies could also be regarded as an extra layer of defense of the body against future coronavirus infections.

Study objective

In this study we will investigate how safe the experimental compounds AER001 and AER002 are and how well they are tolerated when they are used in healthy subjects.

We also investigate how quickly and to what extent AER002 (as a single dose) and AER001 and AER002 (2 single sequential doses) are absorbed, transported, and eliminated from the body. In addition, we look at whether the body has an immune response to AER001 and AER002.

We compare the effects of AER001 and AER002 with the effects of a placebo.

AER001 and AER002 have not been used in humans before. They have been extensively tested in the laboratory and on animals.

Study design

Part 1&2:
The study will take about 12 months from the screening visit until the end of study visit.

Screening -> Day -21 up to Day -2
Treatment period Part 1 - Arrival -> Day -1
Treatment period Part 1 - In-house stay -> Day -1 up to Day 2
Treatment period Part 1 - Departure -> Day 2
Treatment period Part 1 - Follow-up visits* -> Day 8, 15, 29, 57, 85, 169, 223, 281
End of study visit -> Day 337

*If subjects received placebo, Day 85 is the last day they have to come to the research center. They will be called on Days 169, 225, 281, and 337 to check their health.

Part 3:
The study will take about 7,5 weeks from the screening visit until the end of study visit.

Screening -> Day -21 up to Day -2
Treatment period - Arrival -> Day -1
Treatment period - In-house stay -> Day -1 up to Day 2
Treatment period - Departure -> Day 2
Treatment period - Follow-up visits* -> Day 8
End of study visit -> Between Day 28 and 30

Intervention

Part 1: 1 single intravenous infusion of AER002 or placebo (100, 300, 600 or

1200 mg).

Part 2: 2 intravenous infusions one right after each other, one with AER002 or placebo and one with AER001 or placebo (100, 300, 600 or 1200 mg).

Part 3: 2 intravenous infusions one right after each other, one with AER002 and one with AER001 (300 or 1200 mg).

Study burden and risks

Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula (a tube in a vein in the arm) can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment (bruising) of the puncture site. In individuals, a fainting reaction may be observed during blood draw, and this condition is presented as pallor, nausea and sometimes vomiting, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, over the course of the study, we will take about Part 1 &2: 205 milliliters (mL) Part 3: 94 milliliters (mL) of blood from screening to end of study visit. This amount does not typically 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 subject, extra samples might be taken for possible additional testing. If this happens, the total amount of blood drawn may be more than the amount indicated above.

Nasal sample collection
Nasal samples will be taken deep in the nose in one nostril using a flat absorbent strip on Days 1, 8 and 29. The nasal test taker presses the tip of the volunteers nose up with the thumb and holds the volunteers head with the other fingers. After inserting the strip, hold a finger against the side of the volunteers nostril for about 60 seconds. The volunteer must remove his finger from the nostril before the strip is removed from the volunteers nose. The nasal test may cause discomfort and can give an unpleasant feeling. The volunteer may experience a stinging sensation and the volunteers eyes may become watery. Nasal sensitivity may cause sneezing

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

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)

Inclusion criteria

1. Male or female subjects at least 18 years old and less than 50 years of age at first screening visit.
2. Subject has provided written informed consent prior to any trial-related procedure.
3. SARS-CoV-2 confirmed negative by RT-PCR in a nasopharyngeal, oropharyngeal, or respiratory sample at <= 72 hours before randomization and administration of IMP or placebo on Day 1 (all efforts should be made to complete this test as close as possible to Day 1).

4. Subject is in good health and stable medical condition based on medical history, physical examination, laboratory findings, vital signs and ECG (as assessed by the investigator within 21 days prior to Day 1).
5. Willingness and ability to comply with the protocol.
6. For female subject of childbearing potential with a fertile male sexual partner: the use of an adequate contraception from at least 4 weeks prior to the first administration of the IMPs until 90 days after the last intake of the IMP. Male subjects must agree to use adequate contraception from the first administration of the IMP until 90 days after the last intake of the IMP.
7. BMI of 18.0 to 32.0 kg/m2, inclusive, at screening.
8. Weight: >=50 kg.

Exclusion criteria

1. History of any clinically significant medical condition, as assessed by the investigator, that may confound the results of the study or poses an additional risk to the subject by study participation.
2. History of any hospitalization (>24 hours) within 30 days of first screening visit.
3. History of infection with HIV, HCV and HBV.
4. History of alcohol or drug abuse as determined by the investigator.
5. History of any significant allergic reaction to prescription or non-prescription drugs or food, as determined by the investigator.
6. Female who is pregnant, lactating, breastfeeding or planning to become pregnant within 90 days after the last intake of IMP.
7. Participation in any clinical research study evaluating another investigational drug or device within 3 months of the first screening visit.
8. The use of other medications with the possibility for adverse reactions and/or difficulties in the interpretation of results, as determined by the investigator.
9. Subjects who have received a COVID-19 vaccine or a booster at least 2 weeks prior to screening or planning to receive the vaccine or the booster prior to Day 29 following the first dose of study drug.

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:	Recruitment stopped
Start date (anticipated):	10-08-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-07-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-11-2022
Application type:	Amendment
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	EUCTR2022-001709-35-NL
CCMO	NL81586.056.22