A Randomized, Double-Blind, Placebo-Controlled, Phase 1 Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Single Ascending Doses of ABBV-47D11 in Adults Hospitalized with COVID-19

Published: 21-12-2020
Last updated: 08-04-2024

To evaluate the safety and tolerability of single ascending doses of ABBV-47D11 in subjects hospitalized with COVID-19.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON50807

Source
ToetsingOnline

Brief title
M20-404

Condition

- Viral infectious disorders

Synonym
Coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG
Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Antibody, Coronavirus, COVID-19, Hospitalized

Outcome measures

Primary outcome

Safety Endpoints (Primary) - up to Day 106

1. Number of Participants With Study-Drug Related Grade 3 or Higher Adverse

Events (AEs)

2. Number of Participants With Study-Drug Related Grade 3 or Higher

Infusion-Related Reactions

Secondary outcome

1. Maximum Observed Serum Concentration (Cmax) of ABBV-47D11 up to Day 85

2. Time to Cmax (Tmax) of ABBV-47D11 up to Day 85

3. Area Under the Serum Concentration-Time Curve (AUC) From Day 1 (0 hour) to

Day 29 (672 hour) (AUC0-672h) of ABBV-47D11

4. Terminal Phase Elimination Half-Life (t1/2) of ABBV-47D11 up to Day 85

5. AUC From Time 0 to Infinity (AUCinf) of ABBV-47D11 up to Day 85

6. Detection of Anti-Drug Antibodies (ADA) up to Day 85

7. Detection of Neutralizing Anti-Drug Antibodies (nADA) up to Day 85

8. AUC for Change From Baseline (Day 1) in SARS-CoV-2 Ribose Nucleic Acid (RNA)

Reverse Transcription-Polymerase Chain Reaction (RT-PCR) through Day 29

9. Time to Negative SARS-CoV-2 by RT-PCR up to Day 29

10. Negative SARS-CoV-2 RNA by RT-PCR up to Day 15

Study description

Background summary

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Lung failure is the main cause of death related to COVID-19 infection. The main objective of this study is to evaluate the safety and tolerability of ABBV-47D11 in participants hospitalized with COVID-19 infection. In addition, this study will evaluate the pharmacokinetics (how the body handles the study drug) and anti-viral activity of the study drug.

Study objective

To evaluate the safety and tolerability of single ascending doses of ABBV-47D11 in subjects hospitalized with COVID-19.

Study design

Randomized, double-blind, placebo-controlled ascending dose study.

Intervention

Participants will receive single intravenous (into the veins) infusion of ABBV-47D11 or placebo of Day 1.

Study burden and risks

There may be higher treatment burden for participants in this trial compared to their standard of care. The effect of the treatment will be checked by medical assessments, blood tests, nasal swabs and presence of side effects.

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. Adult, at least 18 years old, weighing at least 45 kg
2. Confirmed SARS-CoV-2 infection based on initial nucleic acid or antigen testing from respiratory swab, saliva, or other bodily fluid within 7 days prior to randomization (note: timing based on date of test result)
3. Must have >= 1 symptom associated with COVID-19 (e.g., fever, chills/sweats, cough, shortness of breath/dyspnea, sore throat, fatigue, dyspnea, myalgia, headache, congestion, gastrointestinal symptoms [nausea, vomiting, diarrhea], new loss of taste or smell) with an onset of <= 8 days prior to randomization AND evidence of lower respiratory tract infection by clinical assessment or imaging
4. Hospitalized or plans for hospital admission due to COVID-19 at the time of randomization

Exclusion criteria

1. Must not have an oxygen saturation (SpO2) < 88% on room air at rest for 5 minutes OR ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO2/FiO2) <= 200 mmHg at randomization
2. Not requiring high-flow oxygen therapy/non-invasive or invasive mechanical

ventilation/ECMO or anticipated impending need for high-flow oxygen therapy/non-invasive or invasive mechanical ventilation/ECMO

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:	Will not start
Enrollment:	2
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ABBV-47D11
Generic name:	ABBV-47D11

Ethics review

Approved WMO Date:	21-12-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-01-2021
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	27-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-04-2021
Application type:	Amendment
Review commission:	METC NedMec

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	EUCTR2020-005203-39-NL
ClinicalTrials.gov	NCT04644120
CCMO	NL75962.041.20

Study results

Results posted: 29-08-2022

Summary results
Trial never started

First publication
23-08-2022