A two-center, randomized, double-blind, placebo-controlled, phase Ib study to assess the safety, tolerability and immunogenicity of two ascending doses of the candidate vaccine MVA-MERS-S_DF-1 in healthy study subjects

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• To investigate the safety and tolerability of two ascending dose levels and two different dosing intervals of the candidate vaccine MVA-MERS-S_DF-1 in healthy study subjects.• To investigate safety and tolerability of three intramuscular dose...

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

Summary

ID

NL-OMON50932

Source
ToetsingOnline

Brief title
Study to test safety and immune response to a vaccine for MERS

Condition

- Viral infectious disorders

Synonym
Middle Eastern Respiratory Syndrome (MERS)

Research involving

Human

Sponsors and support

Primary sponsor: University Medical Center Hamburg-Eppendorf
Source(s) of monetary or material Support: CEPI;Norway

Intervention

Keyword: immunogenicity, MERS, Safety, Vaccine

Outcome measures

Primary outcome

• Overall safety and tolerability of two ascending dose levels and two

different dosing intervals of MVA MERS S_DF-1 administered at three time points

• Frequency and severity of local injection site reactogenicity signs and

symptoms

• Occurrence and frequency of adverse events

• Change from baseline safety laboratory parameters

Secondary outcome

• Humoral immunity: Magnitude of MERS-S-specific antibody responses (ELISA and

neutralization assays) monitored in approved laboratories

Study description

Background summary

MERS is a potentially fatal disease under tight epidemiologic control by the WHO and currently with-out registered prevention or treatment options. The first case of MERS-CoV infection was identified in a patient with acute pneumonia and renal failure in the Kingdom of Saudi Arabia (KSA) in June 2012 [ ]. As of Augustus 2021, 2578 laboratory-confirmed cases of MERS-CoV and 888 deaths have been reported, resulting in a case-fatality rate of 34.4% (WHO Situation Re-port). MERS-CoV shows an expanding geographical distribution.

While infections have been mainly observed in the Middle East, 27 countries have reported MERS cases [ ]. To date three cases have been imported to Germany, all with fatal outcome.

Study objective

• To investigate the safety and tolerability of two ascending dose levels and two different dosing intervals of the candidate vaccine MVA-MERS-S_DF-1 in healthy study subjects.
• To investigate safety and tolerability of three intramuscular dose administrations of the candidate MVA-MERS-S_DF-1 vaccine in healthy study subjects using the immunization schedule D0/D28/D224 or D0/D56/D224

Study design

Two-center, randomized, double-blind, placebo-controlled, dose-finding phase Ib study with an open-label run-in phase

Intervention

Vaccination with MVA-MERS-S_DF1

Study burden and risks

Participation in a Phase Ib study may not have a therapeutic benefit for healthy subjects. To the best of our knowledge, the study drug appears to be safe and no serious side effects are expected in this study. The MVA vaccine vector used has been widely used (more than 6,500 individuals, including children, cancer patients, and immune-compromised patients) in clinical trials for other infectious diseases. No unexpected side effects were found. Side effects are also not expected from the antigen introduced into the vector. No SAEs were found during the first small phase Ia study testing MVA-MERS-S
The results of the preclinical studies show a favorable safety and tolerability profile. The chosen study design for the sequential dosing of Part A and Part B is considered sufficient to ensure the safety of the subjects.
Vaccine recipients may benefit from protection against future MERS outbreaks. However, at this stage of vaccine development, participants are strongly advised not to consider themselves protected against MERS after vaccination.
In summary, preclinical and clinical results indicate a favorable safety and tolerability profile. Taking into account the safety measures to minimize the risks to study participants, exposure of healthy subjects to the MVA-MERS-S vaccine is justified, as the potential risks and harms to study participants do not outweigh the potential benefits for medical research, medical practice and ultimately for individuals at risk of MERS infection.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1) Written informed consent form.
2) Healthy male and female subjects aged 18-55 years.
3) No clinically significant acute health problems as determined from medical history and physical examination at screening visit.
4) Body mass index 18.5 - 30.0 kg/m2 and weight > 50 kg at screening.
5) Non-pregnant, non-lactating female with negative pregnancy test.
6) Females who agree to comply with the applicable contracep-tive requirements of the protocol.

Exclusion criteria

1) Receipt of vaccination against MERS in medical history.

2) Receipt of any vaccine from 2 weeks prior to each trial vac-cination (4 weeks for live vaccines) to 3 weeks after each trial vaccination.
3) Known allergy to the components of the MVA-MERS-S_DF-1 vaccine product.
4) Evidence in the subject*s medical history or in the medical examination that might influence either the safety of the sub-ject or the absorption, distribution, metabolism or excretion of the investigational product.
5) Any confirmed or suspected immunosuppressive or immuno-deficient condition, cytotoxic therapy in the previous 5 years, and/or diabetes.
6) Any chronic or active neurologic disorder, including seizures and epilepsy, excluding a single febrile seizure as a child.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-10-2021
Enrollment:	72
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Genetic modified organism
Product type:	Medicine
Brand name:	MVA-MERS-S_DF-1

Ethics review

Approved WMO Date:	28-10-2020
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-09-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	13-12-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-12-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-12-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-01-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-04-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	16-05-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-07-2022
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-000715-83-NL
ClinicalTrials.gov	NCT04119440
CCMO	NL75312.000.20