Monoclonal antibodies as a treatment for Lassa virus

Published: 24-04-2023
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The primary objective of the proposed study is to isolate and characterize neutralizing Lassa-specific monoclonal antibodies from LASV recovered individuals.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON53355

Source
ToetsingOnline

Brief title
Counteract

Condition

- Viral infectious disorders

Synonym
Lassa Virus Infection, viral hemorrhagic fever

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Lassa Virus, monoclonal antibodies, neutralizing antibodies

Outcome measures

Primary outcome

Neutralization potency and breadth of monoclonal antibodies derived from LASV individuals who have recovered from LASV infection as assayed in neutralization assays using lentiviral vectors pseudo-typed with Lassa GP protein

Secondary outcome

- Percentage Lassa GP positive memory B cells as assayed by FACS (clonality) using Lassa GP protein labelled in different colors

- Sequence screening of the most promising LASV monoclonal antibodies

Study description

Background summary

Lassa Virus (LASV) is an Old-World Arenavirus and the causative agent of Lassa fever, a viral hemorrhagic fever that is endemic in parts of West Africa. Recent years have seen several outbreaks of Lassa fever with high mortality rates. The LASV also belongs to the highly pathogenic Risk Group 4 (RG4) viruses that may be used as biological warfare or terrorism agents. Recent animal studies demonstrated that administration of neutralizing antibodies (NAbs) isolated from people previously infected with LASV conferred 100% protection against a LASV challenge (1-3). Monoclonal antibodies (MAbs) have been successfully employed to prevent and treat viral infections such as SARS-CoV-2, RSV, Ebola, influenza and rabies in clinical phase testing and in addition, MAbs have an excellent safety record. We hypothesize that the isolation and characterization of LASV-specific antibodies will provide an avenue for the development of targeted prevention and treatment of LASV hemorrhagic fever.

Study objective

The primary objective of the proposed study is to isolate and characterize neutralizing Lassa-specific monoclonal antibodies from LASV recovered individuals.

Study design

- Observational study with 5 healthy volunteers in 5 years time
- Participants are recruited by Prof. Grobusch in the Tropencentrum of the Amsterdam UMC
- we will conduct a medical history and physical examination and obtain information regarding results of previous Lassa Virus infection
- we will perform a one timepoint blood withdrawal via venapuncture

Study burden and risks

The main adverse reactions related to phlebotomy are hematomas, a slightly increased risk of infection and vasovagal complaints or vasovagal collapse.

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

- Written informed consent to store samples and perform genetic testing.
- Age >= 18 years
- Individuals who have experienced PCR proven LASV infection and minimally 4 weeks post-infection

Exclusion criteria

- Mental disorder that in the view of the investigator would interfere with adherence to the treatment or the study procedures, or the decision to participate in the study.
- Immunosuppressive medication or other diseases associated with immunodeficiency.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-07-2023
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2023
Application type:	First submission

Review commission: METC Amsterdam UMC

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
CCMO	NL83461.018.22