

# Monoclonal antibodies as a treatment for Lassa virus

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	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

### Public

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Meibergdreef 9  
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### Scientific

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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  $\geq 18$  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

## 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