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Dengue monoclonal antibody Phase III randomised double-blind clinical trial for the treatment of symptomatic dengue in children and adult participants

Submission date
07/11/2025

Recruitment status
Not yet recruiting

Registration date
12/11/2025

Overall study status
Ongoing

Last Edited
11/11/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dengue is a viral illness spread by mosquitoes and affects millions of people each year, especially in tropical and subtropical regions. While many people recover without complications, some develop severe symptoms that can lead to hospitalization or even death. Currently, there is no specific treatment for dengue—only supportive care to manage symptoms.
This study aims to test a new potential treatment: a monoclonal antibody called SII Dengue mAb. Monoclonal antibodies are lab-made proteins that help the body fight infections. SII Dengue mAb is designed to neutralize all four types of dengue virus and may help people recover faster and avoid severe illness.
The purpose of this study is to find out whether a single dose of Dengue-mAb given through an intravenous (IV) infusion can safely and effectively reduce the time it takes for people with dengue to recover, and whether it can prevent the disease from getting worse.

Who can participate?
People can take part in this study if they meet the following conditions:
1. They are at least 5 years old.
2. They have symptoms of dengue and a positive test result for dengue (either NS1 antigen or PCR test).
3. Their symptoms started within the last 72 hours.
People will not be able to participate if they already have severe dengue, certain warning signs, serious medical conditions, allergies to the study drug, or have recently received certain vaccines or treatments.

What does the study involve?
This is a Phase III clinical trial, which means the treatment has already been tested in earlier studies and is now being evaluated in a larger group of people.
Participants will be randomly assigned to one of two groups:
• Group 1 will receive Dengue-mAb (the study drug).

• Group 2 will receive a placebo (a harmless solution that looks like the study drug but has no active ingredients).
Both treatments are given as a single IV infusion on the first day of the study. The infusion lasts about 1 hour, and participants will be monitored closely afterward.
After treatment, participants will have daily follow-up visits for 6 days, and possibly longer if symptoms continue. There will also be a visit on Day 28 and a phone call at Month 4 to check on their health and recovery.
During the study, doctors will monitor participants' symptoms, vital signs, blood tests, and other health indicators. The study will look at how quickly participants recover, whether they develop severe symptoms, and whether the treatment is safe.

What are the possible benefits and risks of participating?
Benefits
• Participants may recover faster from dengue.
• The treatment may reduce the risk of developing severe dengue.
• Participants will receive close medical monitoring and care during the study.
Risks
• As with any medication, there may be side effects, such as reactions to the infusion (e.g. fever, rash, or fatigue).
• Blood tests and other procedures may cause minor discomfort.
• There is a chance the treatment may not work or may cause unexpected effects.
All participants will receive standard supportive care for dengue, regardless of which group they are in.

Where is the study run from?
This study is sponsored by the Drugs for Neglected Diseases initiative (DNDi), based in Geneva, Switzerland. The trial will be conducted at multiple hospitals and research centers in Brazil, Malaysia, and Thailand.

When is the study starting and how long is it expected to run for?
The study is expected to start in Q3 2026 and will run for approximately 4 months for each participant. The overall trial is expected to last approximatively 3 years, depending on how quickly participants will be enrolled.

Who is funding the study?
The study is funded and sponsored by the Drugs for Neglected Diseases initiative (DNDi), a non-profit organization that develops treatments for diseases affecting vulnerable populations.

Who is the main contact?
The medical lead for the study is:
Dr. André Siqueira, MD, PhD
Head of Dengue Global Programme
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Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
DNDi-DmAb-01-DEN

Study information

Scientific Title
A parallel-group, double-blind, randomised, two arms, placebo-controlled, multicentre Phase III clinical trial to evaluate the efficacy (time reduction to sustained recovery) and safety of a single-dose intravenous infusion of dengue monoclonal antibody in male and female children aged ≥5 years and adults aged ≥18 years with symptomatic dengue

Study objectives
Demonstrate that Dengue monoclonal antibody compared to placebo reduces the time to sustained recovery from dengue fever

Ethics approval required
Ethics approval required

Ethics approval(s)
1. notYetSubmitted

2. notYetSubmitted

3. notYetSubmitted

Study design
Multicentre parallel-group double-blind randomized placebo-controlled phase III interventional clinical trial with allocation by IVRS and masking of participants and clinical assessors

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Dengue

Interventions
Participants will be randomized in a 1:1 ratio using an Interactive Voice Response System (IVRS) into one of two study arms: SII Dengue mAb or matching placebo. In Arm 1, participants will receive a single intravenous infusion of Dengue-mAb (VIS513) at a dose of 6 mg/kg over 1 hour, with the possibility of extending up to 3 hours in case of infusion-related adverse events. In Arm 2, participants will receive a matching placebo (formulation buffer without active ingredient) at 0.24 mL/kg body weight, administered under the same conditions.
All participants will be followed for a total duration of up to 4 months, including:
* Daily visits from Day 2 to Day 7 (intensive follow-up),
* Optional daily visits from Day 8 to Day 27 if dengue symptoms persist,
* A visit on Day 28,
* A phone follow-up at Month 4 for final safety assessment and evaluation of late symptoms.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
SII Dengue mAb

Primary outcome(s)
Time to sustained recovery is measured using clinical and laboratory assessments including temperature monitoring, haematocrit stability, platelet count, and absence of dengue warning signs and severe dengue criteria, assessed daily from Day 1 to Day 28.

Key secondary outcome(s))
1. Treatment-emergent adverse events (TEAEs) are measured using clinical assessments and laboratory tests from Day 1 to Month 4
2. Serious adverse events (SAEs) are measured using clinical assessments and investigator

reports from Day 1 to Month 4
3. Dengue viral load reduction is measured using RT-qPCR at baseline and 24 hours post-treatment
4. Occurrence of dengue warning signs is measured using clinical assessments (including abdominal pain, persistent vomiting, mucosal bleeding, fluid accumulation, liver enlargement, and hematocrit/platelet changes) from Day 1 to Day 28
5. Occurrence of severe dengue is measured using ultrasound and clinical assessments (including shock, respiratory distress, severe bleeding, organ failure) from Day 1 to Day 28
6. Hospitalisation or death due to dengue progression is measured using medical records and clinical assessments from Day 1 to Day 28

Completion date
30/06/2029

Eligibility

Key inclusion criteria
1. At least 5 years of age inclusive, at the time of signing the informed consent
2. Diagnosed for Dengue by NS1 antigen or PCR positive
3. Start of investigational medicinal product (IMP) infusion within 72 hours of onset of any clinical symptom of dengue

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
5 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Presence of dengue warning signs
2. Presence of severe dengue criteria
3. Clinically unstable medical conditions that may interfere with drug metabolism, pose a risk during participation, or affect data interpretation
4. Known allergies or hypersensitivity to humanized monoclonal antibodies or any component of the investigational product

5. History or evidence of significant active bleeding or coagulation disorders
6. Recent or planned receipt of live-attenuated vaccines within 28 days prior to dosing or during the follow-up period
7. Recent treatment with biologic agents, including monoclonal antibodies, within 12 weeks or 5 half-lives (whichever is longer) prior to dosing

Date of first enrolment
31/08/2026

Date of final enrolment
28/02/2029

Locations

Countries of recruitment
Brazil

Malaysia

Thailand

Study participating centre
Fiocruz INI - Instituto Nacional de Infectologia Evandro Chagas
Av. Brasil, 4365 - Manguinhos
Rio de Janeiro
Brazil
21040-360

Study participating centre
Siriraj Hospital, Mahidol University
2 Wang Lang Rd, Siriraj, Bangkok Noi
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Study participating centre
Klang Health Clinic (Anika)
112 Jalan Pegawai, Off, Jalan Tengku Kelana
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Sponsor information

Organisation
Drugs for Neglected Diseases Initiative

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Charity

Funder Name
Drugs for Neglected Diseases initiative

Alternative Name(s)
DNDi

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
German Federal Ministry of Research, Technology and Space (BMFTR)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available