

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Eltrombopag Olamine on Platelet Recovery and Bleeding Complications Among Dengue Patients with Severe Thrombocytopenia_ A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of eltrombopag olamine on platelet recovery time and bleeding complications in patients of dengue fever

Design

It is a single-center randomized, double-blind, controlled clinical trial with a parallel group design of 50 patients.

Settings and conduct

This single-center clinical trial will be conducted at the Isolated Dengue Ward of Pak Emirates Military Hospital Rawalpindi. Patients will be randomized using online computer-generated numbers to either a control or intervention group after consent. The manual platelets count, serum albumin, serum ferritin, and lipid profile will be measured at the time of admission and 7 days after intervention, the intervention group will be given oral Tab eltrombopag 25 mg once daily for 03 days while the control group will be oral tablet of glucose for same duration.

Participants/Inclusion and exclusion criteria

Adult patients with dengue fever and thrombocytopenia. Patients with malaria co-infection and severe dengue will be excluded

Intervention groups

The patients in the intervention group will be given Tab eltrombopag 25 mg once daily for 03 days. The control group will receive routine and conservative medical care along with oral tablets of Glucose for 3 days once daily.

Main outcome variables

1. The primary outcome will be platelet recovery time and incidence of bleeding complications amongst the groups. 2. The secondary outcome will be changes in inflammatory markers. Both of the outcomes will be measured on the 7th day after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240208060941N3**

Registration date: **2025-03-26, 1404/01/06**

Registration timing: **retrospective**

Last update: **2025-03-26, 1404/01/06**

Update count: **0**

Registration date

2025-03-26, 1404/01/06

Registrant information

Name

Muhammad Iqbal

Name of organization / entity

Pak Emirates Military Hospital/ National University of Medical Sciences

Country

Pakistan

Phone

+92 342 7007463

Email address

iqbalkharal2934@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-21, 1403/07/30

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Eltrombopag Olamine on Platelet Recovery and Bleeding Complications Among Dengue Patients with Severe Thrombocytopenia_ A Randomized Controlled Trial

Public title

Eltrombopag and Platelet Recovery in Patients with Dengue Fever

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients Dengue NS1 Positive Platelet count less than 100

Exclusion criteria:

MP slide positive Presence of any other warning signs

Age

From **14 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

We used simple randomization to ensure an unbiased and equal chance of assignment for all participants. The unit of randomization was the individual participant, ensuring that each subject's assignment was unaffected by others. The random sequence was generated using a computer-based random number generator (RNG). Allocation concealment was strictly implemented to prevent selection bias. The randomization sequence was stored in a password-protected electronic file, and investigators enrolling participants had no prior access to assignment details.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, investigator, and healthcare providers (doctors and nurses) were blinded. Blinding was achieved by placing the drug (Eltrombopag Olamine) and the placebo in identical white capsules. The medications were prepared by a pharmacist in a separate room that was inaccessible to everyone else. The white capsules, labeled with patient IDs, were provided to the healthcare providers, who administered the medications to the patients according to the labeled IDs, thereby ensuring adherence to the blinding protocol.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committee, Pak Emirates Military Hospital, Rawalpindi

Street address

Abid majeed road

City

Rawalpindi

Postal code

46000

Approval date

2024-10-24, 1403/08/03

Ethics committee reference number

A/28/ERC/169/24

Health conditions studied

1

Description of health condition studied

Dengue Fever

ICD-10 code

A90

ICD-10 code description

Dengue fever [classical dengue]

Primary outcomes

1

Description

Change in platelet counts

Timepoint

7 Days after intervention

Method of measurement

Daily complete blood picture with manual platelet counts

2

Description

Incidence of bleeding complications

Timepoint

Before intervention and daily for 7 days after invention

Method of measurement

Clinical monitoring

Secondary outcomes

1

Description

Inflammatory markers

Timepoint

Day 7 of enrollment

Method of measurement

Serum Ferritin, Serum Albumin and Lipid profile will be monitored

Intervention groups

1

Description

Intervention group: Tab Eltrombopag Olamine 25 mg will be given orally for 3 days once a day alongwith routine medical care.

Category

Treatment - Drugs

2

Description

Control group: Oral Glucose tablets will be given for 3 days once daily alongwith routine medical care as a placebo drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak-Emirates Military Hospital, Rawalpindi

Full name of responsible person

Fatima Masud

Street address

Abid majeed road

City

Rawalpindi

Postal code

46000

Phone

+92 335 2799000

Fax

Email

fatimamasud454@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pak-Emirates Military Hospital

Full name of responsible person

Fatima Masud

Street address

Abid majeed road

City

Rawalpindi

Postal code

46000

Phone

+92 335 2799000

Fax

Email

fatimamasud454@gmail.com

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pak-Emirates Military Hospital

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Pak-Emirates Military Hospital, Rawalpindi

Full name of responsible person

Fatima Masud

Position

Registrar Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Abid majeed road

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 335 2799000

Fax

Email

fatimamasud454@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pak-Emirates Military Hospital, Rawalpindi

Full name of responsible person

Fatima Masud

Position

Registrar Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Abid majeed road

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 335 2799000

Fax**Email**

fatimamasud454@gmail.com

Web page address**Email**

fatimamasud454@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Deidentified Individual Participant Data Set, Study Protocol, Statistical Analysis Plan, and Informed Consent forms will be made available to desirous researchers upon reasonable requests, and after clearance from the institutional data registry body. The said documents will be shared in a non-editable format via email after scrutinizing the need for subject documents by the requesting authorities

When the data will become available and for how long

The data will be available 6 months after the publication of the trial.

To whom data/document is available

The data will be available to researchers and teaching institutes for literary and educational purposes,

Under which criteria data/document could be used

The data will be available for academic, research and literary purposes. It will not be available for commercial use.

From where data/document is obtainable

The data can be obtained via Email from: Dr Fatima Masud Department of Medicine, Pak Emirates Military Hospital Rawalpindi fatimamasud454@gmail.com

What processes are involved for a request to access data/document

Data will be made available on reasonable request, after approval from the data registry department of the institute.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Pak-Emirates Military Hospital, Rawalpindi

Full name of responsible person

Fatima Masud

Position

Registrar Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Abid majeed road

City

Rawalpindi

Province

Punjab

Postal code

46000

Phone

+92 335 2799000

Fax