Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Sponsors / Funding sources

1

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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
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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. Tt 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