

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the high-dose dexamethasone effect versus prednisolone in treatment of immune thrombocytopenic purpura patients

Protocol summary

Study aim

Title: Comparing the high-dose dexamethasone effect versus prednisolone in treatment of immune thrombocytopenic purpura patients

Design

Clinical trial without control group, with parallel groups, without blind and non-random, phase 3 on 36 patients

Settings and conduct

All patients aged 18 years old with immune thrombocytopenic purpura (ITP) who were admitted to the oncology of Imam Khomeini Hospital in Urmia and have not previously been treated

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with ITP, which are newly diagnosed and have been treated and previously no therapies Exclusion criteria: People with life-threatening bleeding such as brain hemorrhage; People with trauma; People who have recent surgery

Intervention groups

Patients with ITP, which are newly diagnosed and have been treated and previously no therapies that it two separate groups are treated with intravenous dexamethasone or oral prednisolone.

Main outcome variables

Duration of admission ; Time to reach a platelet response above thirty thousand

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211111053039N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

fatemeh zahmatyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9856

Email address

zahmatyar.f@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the high-dose dexamethasone effect versus prednisolone in treatment of immune thrombocytopenic purpura patients

Public title

Comparing the high-dose dexamethasone effect versus prednisolone in treatment of immune thrombocytopenic purpura patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ITP, which are newly diagnosed and have been treated and previously no therapies
Exclusion criteria:
People with life-threatening bleeding such as brain hemorrhage
People with trauma
People who have recent surgery

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of URMIA University of Medical Sciences

Street address

Emergency Alley, Resalat Blvd

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URMIA

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-11-06, 1400/08/15

Ethics committee reference number

IR.UMSU.REC.1400.293

Health conditions studied

1

Description of health condition studied

Immune thrombocytopenic purpura

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

platelets count

Timepoint

daily

Method of measurement

complete blood count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: dexamethasone intravenous 40 mg daily to 4 days

Category

Treatment - Drugs

2

Description

Intervention group: edible prednisolone of 1 mg/kg body weight daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fatemeh Zahmatyar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

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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

Oroumia University of Medical Sciences

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**

Oroumia University of Medical Sciences

Full name of responsible person

Fatemeh Zahmatyar

Position

Internal medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available