

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison between efficacy of multiple courses of high-dose dexamethasone therapy and single course of high dose dexamethasone in the treatment of newly diagnosed primary immune thrombocytopenia

Protocol summary

Summary

Objective: Comparison the efficacy of multiple courses of high-dose dexamethasone with single course of high dose dexamethasone in the treatment of newly diagnosed primary immune thrombocytopenia Design: An interventional double blind randomized clinical trial was designed in Ali-Ebne Abitalib (A) Hospital in Zahedan. Setting and conduct: All Primary and newly diagnosed immune thrombocytopenia patients in hematology oncology ward in Ali-Ebne Abitalib (A) were evaluated. Participants: All Primary and newly diagnosed immune thrombocytopenia patients in Ali-Ebne Abitalib (A) Hospital in Zahedan enrolled the study. Inclusion criteria: Platelet count less than 20000; platelet count more than 20000 in cases with bleeding. Exclusion criteria: comorbidities such as Diabetes, Liver disease, HIV; Previous History of immune thrombocytopenic purpura; recently use of corticosteroids; history of systemic lupus erythmatous; No consent (declining) for participating in study. Intervention: In this clinical trial sampling was by convenient method. Overall 40 patients with newly diagnosed immune thrombocytopenic purpura who were admitted to the hematology & oncology ward in Ali-Ebne Abitalib Hospital, were randomly allocated to the two groups, one group receiving single course of dexamethasone plus prednisolone (odd numbers) and another group (pair numbers) receiving 4-6 courses of dexamethasone every 14 days. Data collector did not know anything about allocation of cases, the analysor did not know as well. Main outcome measurements: Platelet count was the main outcome measure in different time intervals and corticosteroid complications were evaluated and were collected. Data were analyzed by SPSS ver 19 using Chi-square and Cochran.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110424881N1**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Zahra Sepehri

Name of organization / entity

Zabol university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 0768

Email address

sepehri_z@zsbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental (Grant from deputy of research in Zahedan University of Medical Sciences),

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between efficacy of multiple courses of high-dose dexamethasone therapy and single course of high dose dexamethasone in the treatment of newly diagnosed primary immune thrombocytopenia

Public title

Efficacy of frequent high dose dexamethasone in treatment of primary immune thrombocytopenic purpura

Purpose

Treatment

Inclusion/Exclusion criteria

All Primary and newly diagnosed immune thrombocytopenic purpura patients enrolled the study. Inclusion criteria: Platelet count less than 20000; platelet count more than 20000 in cases with bleeding. Exclusion criteria: comorbidities such as diabetes; liver or renal disease; HIV; Previous history of immune thrombocytopenic purpura; recently use of steroids; history of systemic lupus erythmatous; No consent (declining) for participating in study

Age

From **15 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Zahedan university of medical sciences

Street address

Hesabi square

City

Zahedan

Postal code

9816743463

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

Zums.1.REC.1392.956

Health conditions studied**1****Description of health condition studied**

Newly diagnosed immune thrombocytopenic purpura

ICD-10 code

D69.3

ICD-10 code description

Immune thrombocytopenic purpura

Primary outcomes**1****Description**

Platelet count

Timepoint

Monthly till 12 months after treatment course

Method of measurement

Cell Blood Count; Platelet count

Secondary outcomes**1****Description**

Blood pressure

Timepoint

Monthly after treatment and every 15 min during dexamethasone courses

Method of measurement

By manometer

Intervention groups**1****Description**

Intervention: The group of patients who received 4-6 courses of high dose dexamethasone every 14 days

Category

Treatment - Drugs

2**Description**

Control: The group of patients who received single course of dexamethasone plus oral prednisolone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Ebne Abitalib Hospital

Full name of responsible person

Zahra sepehri

Street address

Rajae street,

City

Zabol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Science

Full name of responsible person

Dr Houshang Rafighdoost

Street address

Number 10, Hesabi square, Pardis of the University

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Zahra Sepehri

Position

Vice Chancellor for Research, Assistant Professor

Other areas of specialty/work

Street address

Number 123, Rajae street

City

Zabol

Postal code

9861611558

Phone

+98 54 3223 0768

Fax

+98 54 3223 0770

Email

Sepehri_za@zbmu.ac.ir

Web page address

Www.zbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

MohammadAli Mashhadi

Position

Full Professor

Other areas of specialty/work

Street address

Number101, Hesabi square

City

Zahedan

Postal code

9813636543

Phone

+98 54 3223 1375

Fax

Email

Mamashhadi67@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Zahra Sepehri

Position

Vice Chancellor for Research

Other areas of specialty/work

Street address

Number 123, Rajae street

City

Zabol

Postal code

9861611558

Phone

+98 54 3223 0768

Fax

Email

Sepehri_za@zbmu.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty