

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of “Pardihan” syrup on platelet count: a randomized double-blind placebo controlled clinical trial

Protocol summary

Study aim

Determining the effect of Pardihan syrup on platelet count; Determining the effect of Pardihan syrup on hemoglobin

Design

This study is a double-blind, randomized, placebo-controlled clinical trial on 32 patients with thrombocytopenia in the clinic of Mostafa Khomeini Hospital. Laboratory tests are used to diagnose thrombocytopenia. 32 codes were randomized with Excel software

Settings and conduct

Patients with a history of thrombocytopenia are referred for testing of blood samples by experienced staff of Mostafa Khomeini Hospital. The consent form of participation in the research project is also completed by patients. Relevant questionnaires are completed. Pardihan and placebo are provided by the manufacturer with similar containers. Special codes are inserted on the package that will be kept confidential until the end of the study. So that the project partners will not be aware of the internal content of the drug packaging. Patients received the number and entered the study in order. Take one tablespoon every 8 hours for 4 weeks. At the beginning of the study and after 2, 4 and 6 weeks, the blood sample is taken again by the staff and the test results are checked by the treating physician. The quality of life questionnaire will be completed again at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria All patients with a diagnosis of thrombocytopenia; Signing a informed consent form; over the age of 18 exclusion criteria Patients with severe platelet depletion who are taking Nplate; have allergic to medicinal plants.

Intervention groups

Pardihan Group as a medicine has a license from the Food and Drug Administration of the country No. 90234/665 The control group was prepared as a placebo

with the same appearance of the drug but safe by pharmacists.

Main outcome variables

platelet count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081024001391N3**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

Mohsen Naseri

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 6646 4320

Email address

naseri@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

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
Effect of "Pardihan" syrup on platelet count: a randomized double-blind placebo controlled clinical trial

Public title
Effect of "Pardihan" syrup on platelet count

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with a diagnosis of thrombocytopenia Signing a informed consent form Age over 18 years
Exclusion criteria:
History of allergy to medicinal plants components Use of nplate drug

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly assigned into 2 groups in a 1:1 ratio using block randomization method with a block length of 2 by PROC PLAN of SAS 9.4. An independent statistician generates the randomization number sequence. The drug codes will be attached after the manufacturing and packaging of the experiment treatment and placebo. Then, allocation concealment will be done using the SNOSE method. The drugs will be allocated sequentially according to the screening order of the patients. Group assignment will be kept in an opaque and sealed envelope and will be opened after data analysis by another statistician.

Blinding (investigator's opinion)
Double blinded

Blinding description
The coding is done in two groups and placebo by a person who does not interfere in the plan and keeps the codes confidential. Until the end of the study, the researcher, doctor and project colleagues are not aware of it. The medicine and the placebo are similar in appearance, packaging, color and smell.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, In front of the holy of Imam,Persian Gulf Highway,

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.SHAHED.REC.1399.053

Health conditions studied

1

Description of health condition studied

Patients with thrombocytopenia

ICD-10 code

D69.6

ICD-10 code description

Thrombocytopenia, unspecified

Primary outcomes

1

Description

platelet counts and hemoglobin

Timepoint

Take the drug for 4 weeks. Measurements are taken after 2, 4 and 6 weeks.

Method of measurement

Blood test (CBC)

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before starting the study; After 6 weeks (end of study)

Method of measurement

Intervention groups

1

Description

Intervention group: Pardihan medicine is a combination of grape juice, apple and basil produced by Sanabel Daroo Company with a license from the Food and Drug Administration of the country No. 90234/665 in January 2016. Take one tablespoon every eight hours for up to 4 weeks. In addition to medication, patients also receive their routine treatments including folic acid and B12 ampules.

Category

Treatment - Drugs

2

Description

Control group: The placebo is provided by Sanabel Daroo Company. Take one tablespoon every eight hours for up to 4 weeks. In addition to placebo patients receive their routine treatments including folic acid and B12 ampules.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Jalodin Shams

Street address

No. 9, Italy St, Palestine St, Keshavarz Boulevard,
Valiasr Square

City

Tehran

Province

Tehran

Postal code

1416643491

Phone

+98 21 8896 6130

Email

info@mkht.ir

Web page address

http://mkht.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Street address

No. 1471, North Kargar Street, Enghelab Square

City

Tehran

Province

Tehran

Postal code

1417953836

Phone

+98 21 6646 4320

Fax

+98 21 6643 4323

Email

tmctrc@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 1471, Headquarters of Shahed University
Research Centers, North Kargar St. Enghlab square

City

Tehran

Province

Tehran

Postal code

1417953836

Phone

+98 21 6646 4320

Email

naseri@shahed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

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Position

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City

Tehran

Province

Tehran

Postal code

1417953836

Phone

0098216646432021

Email

naserishahed@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mohsen Naseri

Position

Associate professor

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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

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Participant Data File (IPD): After identifying individuals, the analysis data will be presented. Study Protocol: Published as an article. Clinical study report: published as an article.

When the data will become available and for how long

6 months after printing the results in the form of an article

To whom data/document is available

Researchers working in institutions and individuals in the industrial sector can apply to a scientific respondent

Under which criteria data/document could be used

It is possible to use the documents after publishing the extracted article with a scientifically responsive opinion.

From where data/document is obtainable

Email: naseri@shahed.ac.ir naserishahed@yahoo.com

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

The email will be reviewed by the applicant at least two days after the application is sent and will be answered within a week.

Comments