

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of the combination of hydroalcoholic extracts of *Tribulus terrestris*, *Platanus* leaves and *Medicago sativa* on increasing production of platelets and other blood products in patients with thrombocytopenia: A Randomized Double-Blind Clinical Trial

Protocol summary

Study aim

Determining the effect of the combination of hydroalcoholic extracts of *Tribulus terrestris*, *Platanus* leaves and *Medicago sativa* on increasing production of platelets and other blood products in patients with thrombocytopenia

Design

A clinical trial, with a control group, with a parallel group, double-blind, randomized, line-up phase on 40 patients. A random sequence will be generated using the site: <https://www.sealedenvelope.com>.

Settings and conduct

The study population is the patients with thrombocytopenia who refer to the blood and cancer clinic, which is confirmed by a doctor specializing in blood and cancer.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of the patient, age between 18 and 75 years, platelet count test below 150 thousand, no spontaneous bleeding, no pregnancy, completion of the informed consent form, Exclusion criteria: Reduction of platelets below 10,000, with active bleeding, pregnancy

Intervention groups

The drug is taken by the patient in the form of 500 mg tablets 3 times a day (1.5 grams per day) for 7 days. The placebo group also receives the placebo with the same volume and 3 times a day.

Main outcome variables

Platelet: White blood cells: Red blood cells: Hemoglobin: Neutrophil: Lymphocyte: Eosinophil: Monocyte

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230926059519N1**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Mohammad hassan Karamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3843 0313

Email address

mhasankaramian8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of the combination of

hydroalcoholic extracts of Tribulus terrestris, Platanus leaves and Medicago sativa on increasing production of platelets and other blood products in patients with thrombocytopenia: A Randomized Double-Blind Clinical Trial

Public title

Investigating the effect of the Tribulus terrestris, Platanus leaves and Medicago sativa in thrombocytopenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of the patient
Age between 18 and 75 years
Platelet count test below 150 thousand
No spontaneous bleeding
No pregnancy
Completing the informed consent form

Exclusion criteria:

- Reduction of platelets below 10,000 and the need for hospitalization
Active bleeding

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used using blocks of 4. A third person who is not involved in the process of taking patients and evaluating patients will create a random sequence using the site: <https://www.sealedenvelope.com> and based on the sample size, 10 blocks of 4 will be created. Each patient will be given a unique code that can be created on this site. Therefore, concealment is observed and the people involved in the study do not know in which group the next person will be placed and they will not know about the random sequence and only the statistics consultant will know about the random sequence and the codes will remain with them. The study is double-blind and the drugs are prepared in identical containers, and none of the patients and the person who evaluates the patients will know what drug was received. Medicines are sealed and an arrangement will be adopted that only people of one group will visit on that day during the re-evaluation and this work will be planned by the statistics consultant who knows about the codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind and the drugs and placebo are prepared in identical containers, and none of the patients

and the person who evaluates the patients will know what drug was received. Medicines are sealed and an arrangement will be adopted that only people of one group will visit on that day during the re-evaluation and this work will be planned by the statistics consultant who knows about the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-
Kermanshah University of Medical Sciences

Street address

Faculty of Medicine, University Street, Shahid Shiroudi
Boulevard, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6714869914

Approval date

2023-09-03, 1402/06/12

Ethics committee reference number

IR.KUMS.MED.REC.1402.153

Health conditions studied

1

Description of health condition studied

Thrombocytopenia

ICD-10 code

D69.6

ICD-10 code description

Thrombocytopenia, unspecified

Primary outcomes

1

Description

Platelet

Timepoint

The beginning of the study and 7 days later

Method of measurement

Blood test

Secondary outcomes

1

Description

White blood cells

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

2

Description

Red blood cells

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

3

Description

Hemoglobin

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

4

Description

Neutrophil

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

5

Description

Lymphocyte

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

6

Description

Eosinophil

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

7

Description

Monocyte

Timepoint

The beginning of the study and 7 days later

Method of measurement

Complete Blood Count test

Intervention groups

1

Description

Intervention group: The drug is taken by the patient in the form of 500 mg tablets 3 times a day (1.5 grams per day) for 7 days. The drug is a new product of Karzan DaruDarman Company and it is composed of hydroalcoholic extract from each plant in the ratio of 70:20:10 (70% Tribulus terrestris, 20% Platanus leaves, 10% Medicago sativa).

Category

Treatment - Drugs

2

Description

Control group: The drug is given to the patients in the form of tablets with the same weight as the main drug and 3 times a day for 7 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Mehrdad Payandeh

Street address

Next to the medical school, Nurse Blvd., Kermanshah

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6742775333

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Email

irhk@kums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mehrdad Payandeh

Street address

The central building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd, Kermanshah

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info@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Mehrdad Payandeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology and Cancer Specialist
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Person responsible for scientific inquiries

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Name of organization / entity
Kermanshah University of Medical Sciences
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Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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mhasankaramian8@gmail.com

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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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