Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 83 3843 0313

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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
City
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Province
Kermanshah
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6742775333
Phone
+98 83 3427 6300
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
City

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Kermanshah
Postal code
6715847141
Phone
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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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Imam Reza Hospital, Next to the Faculty of Medicine, The end of the nurse blvd, Kermanshah
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Mehrdad Payandeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Blood and Cancer
Street address
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Person responsible for updating data

Contact
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Kermanshah University of Medical Sciences
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Mohammad hassan Karamian
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Medical Student
Latest degree
Medical doctor
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General Practitioner
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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