Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Tribulus terretris aqueous extract on count and function of platelet in Immune Thrombocytopenic Purpura patients

Protocol summary

Summary

According to our previous in vitro and animal model studies, in a one-group before and -after design, we investigated the effect of Tribulus terrestris (TT) aqueous extract on count and function of platelets in immune thrombocytopenic purpura (ITP) patients. The aqueous extract of T.T areal parts was shed dried and formulated in the form of 400 mg capsules. Twenty ITP patients (7 males and 13 females) within the range of 20-40 years old range, recognized as ITP disease, were selected for this study. They had clinical signs of ITP and platelet count of less than 100000 cells/µl. The patients were treated with the dosage of 10 mg/kg, oral consumption, three times a day for 14 consecutive days. The blood samples were taken before treatment and on day 1, 14, and 28 after treatment. Platelets count was measured using a cell counter device. In addition, certain platelet factors level such as platelet factor 4 (PF4), Von Willebrand factor (VWF) and serotonin were determined using the relevant ELISA kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062322884N1**
Registration date: **2017-06-23, 1396/04/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-23, 1396/04/02

Registrant information

Name

Ali Mostafaie

Name of organization / entity

Medical Biology Research Center, Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

A grant from Vice Chancellor for Research and Technology, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-04-10, 1394/01/21

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Tribulus terretris aqueous extract on count and function of platelet in Immune Thrombocytopenic Purpura patients

Public title

The effect of Tribulus terrestris on Immune Thrombocytopenic Purpura

Purpose

Treatment

Inclusion/Exclusion criteria

Non-medication with any drugs such as corticosteroids

Age

From **74 years** old to **54 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
One-group before and after design study

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No 2, Kermanshah University of Medical Sciences, Shahid Beheshti boulevard
City
Kermanshah
Postal code
6714869914
Approval date
2013-02-12, 1391/11/24
Ethics committee reference number
11/91

Health conditions studied

1

Description of health condition studied
Immune Thrombocytopenic Purpura
ICD-10 code
D69.3
ICD-10 code description
Idiopathic thrombocytopenic purpura

Primary outcomes

1

Description
Counts of platelets
Timepoint
Before intervention, one day, two weeks and four weeks after intervention
Method of measurement
Count of platelets and blood cells using cell counter device and report as cells/microliter of blood

2

Description
Platelet factor 4 (PF4) level
Timepoint
Before intervention, one day, two weeks and four weeks after intervention
Method of measurement
Assay of PF4 using ELISA method and report at ng/ml of serum

3

Description
Von Willebrand factor level
Timepoint
Before intervention, one day, two weeks and four weeks after intervention
Method of measurement
Assay using ELISA and report at ng/ml of serum

4

Description
Serotonin level
Timepoint
Before intervention, one day, two weeks and four weeks after intervention
Method of measurement
Assay using ELISA and report at ng/ml of serum

Secondary outcomes

1

Description
Purpura (Skin hemorrhagic spots)
Timepoint
Before intervention, one day, two weeks and four weeks after intervention
Method of measurement
Distribution of spots by visual examination and size of spots by a ruler (mm)

Intervention groups

1

Description
Intervention: Aqueous extract of Tribulus terretris , 400 mg capsules. Dosage: Three capsules a day for 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital , Kermanshah University of Medical Sciences

Full name of responsible person
Dr Ali Mostafaie

Street address
Ayatollah Taleghani Hospital, Shahid Behishti Boulevard

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Kermanshah University of Medical Sciences

Full name of responsible person
Dr Behrooz Hamzeh

Street address
Building No 2 of Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

City
Kermanshah

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 of Kermanshah University of Medical Sciences

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
Kermanshah University of Medical Sciences, Medical Biology Research Center

Full name of responsible person
Dr Ali Mostafaie

Position
PhD, Professor of Immunology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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