

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of effect of *Ocimum basilicum* L. (basil) and *Plantago major* on increased blood platelet in ITP Patients

Protocol summary

Study aim

Evaluation of effect of *Ocimum basilicum* L. (basil) and *Plantago major* on increased blood platelet in ITP Patients

Design

This clinical trial was performed on 50 patients, divided into two groups of 25, including a control group and parallel groups. This study is Double-blind and block randomization method is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Platelet count between 20,000 and 100,000, Do not take painkillers and corticosteroids
Exclusion Criteria: Lupus erythematosus, Antiphospholipid syndrome, CLL, Infectious agents, Recent bone marrow transplantation

Intervention groups

Intervention group: hydroalcoholic extract of *Ocimum basilicum* L. (basil) and *Plantago major*, oral capsule, 400 mg, Three times a day for two months
Control group: placebo containing starch, oral capsule, 400 mg, Three times a day for two months

Main outcome variables

Blood platelet count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N7**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 9435

Email address

p.sharifi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of *Ocimum basilicum* L. (basil) and *Plantago major* on increased blood platelet in ITP Patients

Public title

Evaluation of effect of *Ocimum basilicum* L. (basil) and *Plantago major* on increased blood platelet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Platelet count between 20,000 and 100,000 Do not take painkillers and corticosteroids

Exclusion criteria:

Lupus erythematosus Antiphospholipid syndrome CLL Infectious agents Recent bone marrow transplantation Pregnancy

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, 50 Patients with the desired profile referred to the Tohid Hospital were detached, and by Randomization, Subjects were randomly divided into two treatment and placebo groups using quadatric permutation blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and doctor are not aware of the type of drug (placebo and treatment). Afterwards, drug and placebo will be given confidentially by the relevant expert, and all the information will be recorded separately for each patient and analyzed in the end.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdarán Blvd, Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66117713446

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.MUK.REC.1397/346

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

Immune thrombocytopenic purpura

ICD-10 code

D69.3

ICD-10 code description

Immune thrombocytopenic purpura

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

Blood platelet count

Timepoint

Before intervention, one month after intervention, two months after intervention

Method of measurement

Complete blood count (CBC) test

Secondary outcomes

empty

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

Intervention group: Capsule containing hydroalcoholic extract of Ocimum basilicum L. (basil) and Plantago major at dose of 400 mg three times a day for two consecutive months. These oral capsules are prepared by a reputable pharmacist.

Category

Placebo

2**Description**

Control group: Placebo in capsules at dose of 400 mg three times a day for two consecutive months. These placebo oral capsules contain starch and are prepared by a reputable pharmacist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital

Full name of responsible person

Bayazid Ghaderi

Street address

Tohid Hospital, Geriashan Ave

City

Sanandaj

Province

Kurdistan

Postal code

6616812131

Phone

+98 87 3366 4645

Email

bayazid.g@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Afshin Maleki

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City

Sanandaj

Province

Kurdistan

Postal code

6617713466

Phone

+98 87 3366 4645

Email

maleki43@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Bayazid Ghaderi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Blood and oncology

Street address

Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

6617713466

Phone

+98 87 3366 4645

Email

bayazid.g@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Bayazid Ghaderi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Blood and oncology

Street address

Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

6617713466

Phone

+98 87 3366 4645

Email

bayazid.g@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Pezhman Sharifi

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Microbiology

Street address

Research Department, Tohid Hospital, Tohid Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6616813131

Phone

+98 87 3324 9435

Fax

+98 87 3324 9435

Email

p.sharifi@muk.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable