

# 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**

Pasdaran 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.

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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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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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

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**Full name of responsible person**

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**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Microbiology

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**Email**

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**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