

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### To evaluate effectiveness of Tanacetum parthenium (L) Sch. consumption on blood inflammatory and coagulating indexes

#### Protocol summary

##### Study aim

To evaluate effectiveness of Tanacetum parthenium (L) Sch. consumption on blood inflammatory and coagulating indexes

##### Design

Randomized controlled clinical trial with parallel groups and double blinded.

##### Settings and conduct

This study is conducting in Fasa and participants, researchers and analyzer are blinded to the study groups.

##### Participants/Inclusion and exclusion criteria

Healthy people between 20 and 60 years old who had not consume anti-inflammatory drugs and agree to participate in the study are recruited. And recent history of GI bleeding and/or surgery and side effects are exclusion criteria.

##### Intervention groups

For 2weeks, in drug group; capsules with 250 mg Tanacetum parthenium (L) Sch are administrated 1 time per day. And in control group; capsules with 250 mg corn flour are administrated 1 time per day.

##### Main outcome variables

Bleeding Time Prothrombin Time (PT) Partial Thromboplastin Time (PTT) IL (1beta, 6, 8, 10, 18, 23, 33, 12p70, 17A) INF(alpha,gama) TNF alpha MCP-1

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140715018490N5**  
Registration date: **2018-08-03, 1397/05/12**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

##### Registration date

2018-08-03, 1397/05/12

##### Registrant information

###### Name

Massih Sedigh Rahimabadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3825 6275

###### Email address

sedighrm@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-20, 1397/01/31

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To evaluate effectiveness of Tanacetum parthenium (L) Sch. consumption on blood inflammatory and coagulating indexes

##### Public title

Effectiveness of Tanacetum parthenium on inflammatory and coagulating indexes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

age between 20 and 60 negative hx of D.M negative hx of

major surgery(Under 6 months) negative hx of HTN negative hx of coagulopathy like hemophilia negative hx of liver diseases Satisfaction to participate in the scheme. not use anticoaglant drugs and anti inflammatory drugs such as NSAIDs Not to have bleeding disorders in GI system

**Exclusion criteria:**

positive hx of coagulopathy like hemophilia positive hx of HTN positive hx of major surgery(Under 6 months) positive hx of D.M liver disease such as cirrhosis or hepatitis Age over 60 or under the age of 20 use anticoaglant drugs and anti inflammatory drugs such as NSAIDs Dissatisfaction to participate in the scheme To have bleeding disorders in GI system possible complications

**Age**

From **20 years** old to **60 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blocked Randomized Table

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, researchers and data analyzer were blinded to the study groups. We made the placebo and therapeutic capsules like each other and labeled them by a letter -A and B.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Fasa University of Medical Sciences

**Street address**

Fasa University of Medical Sciences, Ebnesina square, Fasa

**City**

Fasa

**Province**

Fars

**Postal code**

74616-86688

**Approval date**

2017-10-22, 1396/07/30

**Ethics committee reference number**

ir.fums.rec.1396.262

**Health conditions studied**

**1**

**Description of health condition studied**

Healthy individuals

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Prothrombin Time (PT)

**Timepoint**

At the beginning of intervention, 2 weeks and 6 weeks after the beginning of intervention

**Method of measurement**

Venous Blood Test

**2**

**Description**

Partial Thromboplastin Time (PTT)

**Timepoint**

At the beginning of intervention, 2 weeks and 6 weeks after the beginning of intervention

**Method of measurement**

Venous Blood Test

**3**

**Description**

IL-1 $\beta$

**Timepoint**

At the beginning of intervention and 2weeks later

**Method of measurement**

Venous Blood Test

**4**

**Description**

IFN- $\alpha$

**Timepoint**

At the beginning of intervention and 2weeks later

**Method of measurement**

Venous Blood Test

## 5

### **Description**

IFN- $\gamma$

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 6

### **Description**

TNF- $\alpha$

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 7

### **Description**

monocyte chemotactic protein-1

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 8

### **Description**

IL-6

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 9

### **Description**

IL-8

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 10

### **Description**

IL-10

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 11

### **Description**

IL-12p70

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 12

### **Description**

IL-17A

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 13

### **Description**

IL-18

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 14

### **Description**

IL-23

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## 15

### **Description**

IL-33

### **Timepoint**

At the beginning of intervention and 2 weeks later

### **Method of measurement**

Venous Blood Test

## **Secondary outcomes**

### 1

#### **Description**

Satisfaction of patients

#### **Timepoint**

1 month after recruitment

#### **Method of measurement**

visual analog scale

### 2

#### **Description**

Tolerance

#### **Timepoint**

1 month after recruitment

#### **Method of measurement**

visual analog scale

### 3

#### **Description**

Drug side effects

#### **Timepoint**

1 month after recruitment

#### **Method of measurement**

Questionnaire

## Intervention groups

### 1

#### Description

Treatment group: In this group; capsules with 250 mg Tanacetum parthenium (L) Sch are administrated 1 time per day for 2 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

control group: In this group; capsules with 250 mg corn flour are administrated 1 time per day for 2 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fasa University of Medical Sciences

##### Full name of responsible person

Ebrahim Akrami

##### Street address

Fasa University of Medical Sciences, Ebnesina square,  
Fasa

##### City

Fasa

##### Province

Fars

##### Postal code

7461686688

##### Phone

+98 71 5335 0994

##### Fax

+98 71 5335 7091

##### Email

akrami\_e@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Fasa University of  
Medical Sciences

##### Full name of responsible person

Dr. Mojtaba Farjam

##### Street address

Fasa University of Medical Sciences, Ebnesina square,  
Fasa

##### City

Fasa

##### Province

Fars

##### Postal code

7461686688

##### Phone

+98 71 5335 0994

##### Email

akrami\_e@yahoo.com

#### 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, Fasa 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

Fasa University of Medical Sciences

##### Full name of responsible person

Ebrahim Akrami

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

No. 34, Western Sahebolamr Ave., North Safir Blvd.

##### City

Shiraz

##### Province

Fars

##### Postal code

7177846939

##### Phone

+98 71 3820 0533

##### Email

akrami\_e@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Fasa University of Medical Sciences

##### Full name of responsible person

Dr Mohammadreza Ataollahi

##### Position

استاديار

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

**Street address**

Fasa University of Medical Sciences, Ebnesina square,  
Fasa, Fars, Iran

**City**

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**Province**

Fars

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7461686688

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ataollahimr@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Ebrahim Akrami

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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**Postal code**

7177846939

**Phone**

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**Email**

akrami\_e@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Because of ethical considerations

**Study Protocol**

No - There is not 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**

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

**Data Dictionary**

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