Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+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 between20 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 inflamatory 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 cirihosis or hepatitis Age over 60 or under the age of 20 use anticoaglant drugs and anti inflamatory 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-1β

Timepoint

At the beginning of intervention and 2weeks later

Method of measurement

Venous Blood Test

4

Description

IFN-α

Timepoint

At the beginning of intervention and 2weeks later

Method of measurement

Venous Blood Test

5

Description
IFN-γ
Timepoint
At the beginning of intervention and 2 weeks later
Method of measurement
Venous Blood Test

6

Description
TNF-α
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
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7461686688
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Fax
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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
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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
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Person responsible for scientific inquiries

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Position

استادیار

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Ph.D.

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Immunology

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Person responsible for updating data

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Position
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Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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