Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Aug 2026

The effect of urtica dioica leaf extract on tumor necrosis factor alpha, high- sensitivity C- reactive protein, superoxide dismutase, erythrocyte sedimentation rate, blood cell count, calprotectin and quality of life in patient with inflammatory bowel disease compared with the control group that received placebo

Protocol summary

Summary

This study is being undertaken to assess the effect of urtica dioica leaf extract on tumor necrosis factor alpha, high-sensitivity C-reactive protein, superoxide dismutase, erythrocyte sedimentation rate, blood cell count, calprotectin and quality of life in patient with inflammatory bowel disease. This study is a randomized double-blind, placebo- controlled, single center, phase II trial on 64 patients with inflammatory bowel disease confirmed by a specialist, in a period of 3 months in Rasoul's hospital. Inclusion criteria: inflammatory bowel disease in mild and moderate stages, no change in the type and dose of medication during the study, without any other diseases ,non-pregnant or breastfeeding women or non-use of contraceptive pill, not Having edema caused by heart or renal disease, no use of dietary supplements and herbal pills. Exclusion criteria: exacerbation of disease resulting in hospitalization, changes in dosage and type of medication during intervention, sensitivity to nettle. Intervention group will ingest 400mg of nettle extract 3 times a day for 3 months and the control group will similarly ingest placebo 3 times a day. IBDQ-9 questionnaire will be given to patients once at the beginning and again at the end of the 3-month study period. Erythrocyte sedimentation rate, high-sensitivity C-reactive protein, quality of life, white blood cell, superoxide dismutase, platelet, tumor necrosis factor alpha, and calprotectin will be determined by laboratory methods at the beginning and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410062709N30**
Registration date: **2014-11-15, 1393/08/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-15, 1393/08/24

Registrant information

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2016-01-30, 1394/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of urtica dioica leaf extract on tumor necrosis factor alpha, high- sensitivity C- reactive protein, superoxide dismutase, erythrocyte sedimentation rate, blood cell count, calprotectin and quality of life in patient with inflammatory bowel disease compared with the control group that received placebo

Public title
The effect of nettle extract in patients with inflammatory bowel Disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Willingness to participate in the study, inflammatory bowel disease in mild and moderate stages, no change in the type and dose of medication during the study, without any other diseases such as intestinal diseases, known autoimmune diseases, cancer, inflammatory diseases, infectious diseases, non-pregnant or breastfeeding women or non-use of contraceptive pill, not Having edema caused by heart or renal disease, no use of dietary supplements and herbal pills, no use of anticoagulant drugs such as heparin and antibiotics, patients in the study use similar types of drugs. Exclusion criteria: The patient's unwillingness to cooperate, exacerbation of disease resulting in hospitalization, changes in dosage and type of medication during intervention, sensitivity to nettle, compliance rate of less than 90%.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is done by stratified blocked randomization. Placebo in the form of a double-blind to the participants in this study given. Researchers and patients are blinded to the treatment and placebo groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Faculty of Health, Iran University of Medical Sciences, near milad Hospital, Shahid Hemmat Highway, Tehran, Iran

City
Tehran

Postal code

Approval date
2014-10-27, 1393/08/05

Ethics committee reference number
93-03-27-25035

Health conditions studied

1

Description of health condition studied
Inflammatory bowel disease

ICD-10 code
K50, K51

ICD-10 code description
Crohn disease of small intestine, Ulcerative colitis

Primary outcomes

1

Description
Erythrocyte Sedimentation Rate

Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention

Method of measurement
Automation Method (mm/h)

2

Description
High- sensitivity C- reactive protein

Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention

Method of measurement
It is measured by kit (ELISA methods) and the unit is mg/dl.

3

Description
Quality of life

Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
Inflammatory Bowel Disease Questionnaire-Short Form

4

Description
White blood cell
Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
Flow cytometry Method (cells/ml)

5

Description
Superoxide dismutase
Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
It is measured by kit (ELISA methods) and the unit is ng/ml.

6

Description
Platelet
Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
Flow cytometry Method (cells/µl)

7

Description
Fecal calprotectin
Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
It is measured by kit (ELISA methods) and the unit is µg/g.

8

Description
Tumor necrosis factor alpha
Timepoint
At the Beginning of intervention and 3 months after Beginning of the intervention
Method of measurement
It is measured by kit (ELISA methods) and the unit is ng/ml.

Secondary outcomes

empty

Intervention groups

1

Description
Stinging nettle tablet, produced in the company of barijessence, 400 mg tablet, three times a day for 3 months in intervention group
Category
Treatment - Drugs

2

Description
Placebo, tablets containing starch, produced in Tehran University of Medical Sciences, 400 mg tablet, three times a day for 3 months in control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital, Iran University of Medical Sciences
Full name of responsible person
Doctor Shahram Agah
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
7th Floor, Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave., Tehran, Iran.
City
Tehran
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, Iran 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
Iran University of Medical Sciences
Full name of responsible person
Doctor Farzad Shidfar
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Person responsible for updating data

Contact

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