

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

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/ μ l)

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
 μ g/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

Position

Professor

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8862 2706

Fax**Email**

shidfar.f@iums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Doctor Farzad Shidfar

Position

Professor

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code**Phone**

+98 21 8862 2706

Fax**Email**

Shidfar.f@iums.ac.ir

Web page address**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