

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Investigation the effect of achillea millefolium oral supplement on some biochemical and inflammatory blood factors in patients with type 2 diabetes referred to Rafsanjan diabetes clinic, in 2023

Protocol summary

Study aim

Investigation the effect of achillea millefolium oral supplement on some biochemical and inflammatory blood factors in patients with type 2 diabetes referred to Rafsanjan diabetes clinic, in 2023

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 70 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The units of research in this study are 70 patients with type 2 diabetes referred to the diabetes clinic in Rafsanjan, who were included in the study based on the conditions and criteria of entry. The conditions of all the studied patients should be the same, and after checking the mentioned conditions, the patients will be randomly divided into two groups of 35 people. After the three-month period of treatment of the patients, 10 cc of the patients' blood will be taken by a skilled person to measure the cytokine factors in question and also the studied enzymes.

Participants/Inclusion and exclusion criteria

Type 2 diabetes; Age over 40 years; Lack of pregnancy; lack of breastfeeding; Non-participation in another research project; History of diabetes for at least five years; No history of allergies to medicinal herbs

Intervention groups

Intervention: user of yarrow capsules Control: recipient of placebo

Main outcome variables

The possibility of side effects following the oral intake of yarrow extract such as skin itching and hives

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058459N1**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**

Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Vahid Mohammadi-Shahrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 191 1230

Email address

drvahid@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of achillea millefolium oral

supplement on some biochemical and inflammatory blood factors in patients with type 2 diabetes referred to Rafsanjan diabetes clinic, in 2023

Public title

The effect of achillea millefolium on blood inflammatory factors in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having type II diabetes Age over 40 years old Inform consent for participate in the study History of diabetes for at least five years

Exclusion criteria:

Participate in another research project Having other physical illnesses in addition to diabetes Pregnancy and lactation Allergy to medicinal plants

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

Randomized

Randomization description

Random classification by minimization method: In this method, classes are first formed based on the important variables desired by the researcher, which in this study are blood tests, then among the patients who meet the entry criteria, the first samples are randomly selected (on based on lion and line) are included in the study and are placed in one of the groups. For the following examples, the sum of the indicators in two groups is given attention and the sample is assigned to the group that has a lower sum.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs and placebo are similar in shape, packaging, color and smell. In order to blind patients, the pharmacist is asked to identify the drug and the placebo with numbers one and two so that the researcher does not know about the content of the capsules (drug or placebo). Patients are also given the capsules numbered 1 and 2 and the patient also doesn't know about the content of the capsules. The blinding will also be available for the analyzer, and after completing the analysis, the pharmacist will be asked to disclose the content of the capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Central office of Rafsanjan University of Medical Sciences (RUMS), Imam Ali Blvd, Ali Ibn Abitaleb square

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.RUMS.REC.1402.032

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Mean blood inflammatory factors.

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Biochemical autoanalyzer

Secondary outcomes

1

Description

Liver enzymes

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Biochemical autoanalyzer

2

Description

Michigan neuropathy questionnaire

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: In this group, patients receive a 500 mg capsule of achillea millefolium (made by Rafsanjan Asans Daru company) daily for 12 weeks.

Category

Treatment - Other

2

Description

Control group: In this group, patients will receive placebo (a 500 mg capsule of cellulose, made by Rafsanjan Asans Daru company) daily for 12 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of Ali Ebn Abitaleb Hospital

Full name of responsible person

Parisa Balaei

Street address

Ali IBn Abitaleb hospital, Mofateh Blvd, Ali IBn Abitaleb square

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 2282

Email

aliebn_hospital@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

Street address

Central office of Rafsanjan University of Medical Sciences (RUMS), Imam Ali Blvd, Ali Ibn Abitaleb square

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0097

Email

vcrt@rums.ac

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Vahid mohammadi shahrokhi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Faculty of Medicine, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

v_md_sh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Vahid Mohammadi shahrokhi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Faculty of Medicine, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

v_md_sh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Vahid Mohammadi Shahrokhi

Position

Asistant professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Faculty of Medicine, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

v_md_sh@yahoo.com

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

Undecided - It is not yet known if there will be 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

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