

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effect of oral supplement of achillea millefolium on HbA1C and peripheral neuropathy in type 2 diabetic patients

Protocol summary

Study aim

Determination the effect of oral supplement of achillea millefolium on HbA1C and peripheral neuropathy in type 2 diabetic patients

Design

A double blinded, randomized, controlled clinical trial with a parallel group design

Settings and conduct

In this randomized double blind clinical trial, the research population are patients with type 2 diabetes who will referred to the Diabetes Clinic in Rafsanjan. These patients will selected by convenient sampling method and will be assigned to intervention and control groups using minimization methods. The intervention group will receive achillea millefolium for 12 weeks. In the control group, the patients will receive cellulose as a placebo similar to those in the intervention group.

Participants/Inclusion and exclusion criteria

Having type II diabetes, age over 40 years old, inform consent for participate in the study, getting a score above 7 from the Michigan neuropathy questionnaire and history of diabetes for at least five years are inclusion criteria. Participate in another research project, having other physical illnesses in addition to diabetes, having psychiatric diseases, pregnancy, lactation, history of hereditary neuropathies or underlying diseases that cause neuropathy such as chronic uremia, autoimmune diseases (rheumatism, multiple sclerosis, osteoarthritis), allergy to medicinal plants, wounds or infections on the feet, lower extremity amputation and use of anticoagulant drugs are exclusion criteria.

Intervention groups

Intervention group: In this group, patients receive a 500 mg capsule of achillea millefolium, made by Rafsanajn Asans Daru Company, daily for 12 weeks. Control group: In this group, patients will receive placebo (a 500 mg capsule of cellulose, made by Rafsanajn Asans Daru Company), daily for 12 weeks.

Main outcome variables

Peripheral neuropathy, HbA1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150713023190N13**

Registration date: **2022-05-24, 1401/03/03**

Registration timing: **prospective**

Last update: **2022-05-24, 1401/03/03**

Update count: **0**

Registration date

2022-05-24, 1401/03/03

Registrant information

Name

Tabandeh Sadeghi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.sadeghi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral supplement of achillea millefolium on HbA1C and peripheral neuropathy in type 2 diabetic patients

Public title

The effect of achillea millefolium on HbA1C and peripheral neuropathy in diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having type II diabetes Age over 40 years old Inform consent for participate in the study Getting a score above 7 from the Michigan neuropathy questionnaire History of diabetes for at least five years

Exclusion criteria:

Participate in another research project Having other physical illnesses in addition to diabetes Having psychiatric diseases Pregnancy Lactation History of hereditary neuropathies or underlying diseases that cause neuropathy such as chronic uremia Autoimmune diseases (rheumatism, multiple sclerosis, osteoarthritis) Allergy to medicinal plants Wounds or infections on the feet Lower extremity amputation Use of anticoagulant drugs

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization by minimization method: in this method, initially, the patients will categorize based on key variables, such as Michigan neuropathy questionnaire score and HbA1C variables. Afterwards, from the patients who will meet the inclusion criteria, the first participant will place in the intervention or control group by coin flip, and other participants will allocate to the study group with lower total of variables.

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

2022-04-13, 1401/01/24

Ethics committee reference number

IR.RUMS.REC.1401.015

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 of HBA1C

Timepoint

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

Method of measurement

Spectrophotometer device

2

Description

Peripheral neuropathy score

Timepoint

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

Method of measurement

Michigan neuropathy questionnaire

Secondary outcomes

empty

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

Placebo

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Reza Vazirinejad

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Web page address

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

Tabandeh Sadeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable

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

Not applicable