

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The efficacy of *Fumaria parviflora* L. versus gabapentin on uremic pruritus of patients undergoing hemodialysis: A randomized non-inferiority double-blinded active-controlled clinical trial

Protocol summary

Study aim

Investigating the effect of *Fumaria parviflora* L. compared to gabapentin in reducing itching in dialysis patients

Design

Non-inferiority clinical trial, with two parallel groups, randomized, double-blind, phase two on 70 patients, random sequence generator of stata software will be used for randomization.

Settings and conduct

The location of the project is Namazi Hospital Dialysis Center in Shiraz, and patients, researchers, medical personnel and data analysts are blinded.

Participants/Inclusion and exclusion criteria

Adult patients with end stage kidney disease undergoing hemodialysis who suffer from itching and their itching is not controlled and do not have a history of skin disease, seizures, or liver disease and are not allergic to *Fumaria parviflora* L. and Gabapentin

Intervention groups

The first group will receive two grams of *Fumaria parviflora* L. per day for two months, and the second group will receive 100 mg at night, both groups will also receive a placebo to ensure randomization

Main outcome variables

Itching score of patients based on 5D itch score questionnaire; Quality of life score of patients based on DLQI questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121031011341N11**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Mohammad Hashem Hashempur

Name of organization / entity

Fasa University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 8476

Email address

hashempurm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of *Fumaria parviflora* L. versus gabapentin on uremic pruritus of patients undergoing hemodialysis: A randomized non-inferiority double-blinded active-controlled clinical trial

Public title

The efficacy of *Fumaria parviflora* L. versus gabapentin

on pruritus of patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The hemodialysis patient who has uncontrollable pruritus and now at least 1 week doesn't use any antipruritus medication who had pruritus for at least 6 weeks patient must have normal range phosphor and potassium in the past month Parathyroid Hormone (PTH) must be lower than 500 measured visual analogue scale (VAS) score must be four or more

Exclusion criteria:

They do not have liver disease, a history of convulsions, or a specific skin disease that causes itching, and they do not have hemolytic blood disease. Patients who complain of itching for the first time are not included in the study If the patient was taking medication that interacted with gabapentin or Fumaria parviflora L., he was not included in the study Those who are allergic to Fumaria parviflora L. or Gabapentin are not included in the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using stratified block randomization method with unequal blocks (4,6,8). Block random sequence will be created using random sequence generator software. The sequence of allocation blocks will be random. The random allocation ratio will be 1:1, so that for each control, one active case will be present in the study. Based on the randomly generated sequence, each drug/placebo package will be identified with a unique code.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Gabapentin, F. parviflora, and their placebo capsules have the same color, shape, and size. Their container will be labeled by a coordinator (not included in the study team) with nonidentifiable codes. Regarding groups assignment, participants, investigators, caregivers, and data analyzers will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Vice-Chancellery of Research and Technology office, Shiraz University of Medical Sciences, Zand street, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-11-05, 1401/08/14

Ethics committee reference number

IR.SUMS.MED.REC.1401.409

Health conditions studied

1

Description of health condition studied

Uremic pruritus in dialysis patient

ICD-10 code

L29

ICD-10 code description

Pruritus

Primary outcomes

1

Description

Itching score in the 5-D pruritus questionnaire

Timepoint

Before the start of the intervention (the beginning of the study) and two months later (the end of the study)

Method of measurement

5D itch questionnaire

Secondary outcomes

1

Description

Quality of life score in DLQI questionnaire

Timepoint

Before the start of the intervention (the beginning of the study) and two months later (the end of the study)

Method of measurement

DLQI quality of life questionnaire

Intervention groups

1

Description

first intervention group: the patients in this group are given 2 grams of Fumaria parviflora L. in the form of 6 capsules of 330 mg as two capsules three times a day and one placebo capsule is given to them at night

Category

Treatment - Drugs

2

Description

second intervention group: patients in this group are given one capsule of 100 mg of gabapentin at night before going to bed, as well as two placebo capsules three times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Hosseini Seyed Ali

Street address

Namazi square, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4332

Email

hoseiniseyyedali70@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempur

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3235 7282

Email

hashempur@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hosseini Seyed Ali

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Namazi hospital, Namazi square, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4332

Email

hoseiniseyyedali70@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Zand Blvd

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4332

Email

hashempur@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hosseini Seyed Ali

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Namazi hospital, Namazi square, Zand Blvd

City

Shiraz

Province

Fars

Postal code

7193711351

Phone

+98 71 3647 4332

Email

hoseiniseyedali70@gmail.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

Yes - There is 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

Title and more details about the data/document

N/A

When the data will become available and for how long

N/A

To whom data/document is available

N/A

Under which criteria data/document could be used

N/A

From where data/document is obtainable

N/A

What processes are involved for a request to access data/document

N/A

Comments