

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison the Effect of Fumaria Parviflora and Gabapentin in Treatment of Uremic Pruritus in Hemodialysis Patients

Protocol summary

Study aim

This study was designed to evaluate the effect of Fumaria Parviflora capsule and compare it with Gabapentin capsule on the improvement of uremic pruritus in dialysis

Design

In this study, 52 dialysis patients with pruritus were divided into two groups: Fumaria Parviflora capsules and gabapentin (26 patients in each group). The clinical trial phase of this study is 3. How to divide randomly is simple. This study is a two-way blind study. In this study, before the intervention and after 8 weeks of capsule use, the amount of pruritus was measured using the VAS questionnaire.

Settings and conduct

The study site is Arak University of Medical Sciences. First, the pruritus rate of dialysis patients is measured. If they have the conditions to study, they are randomly divided into two groups. One group receives the Fumaria Parviflora capsule and the other group receives the gabapentin capsule. This study is a double-blind study that participants and statistical analysts do not know the groups. At the end of the 8-week intervention phase, the amount of pruritus in these participants are measured again and the effectiveness of the Fumaria Parviflora capsule is compared with that of gabapentin capsule.

Participants/Inclusion and exclusion criteria

Dialysis patients with pruritus are included in the study. These patients should not have heart disease. If a participant becomes allergic to the Fumaria Parviflora capsule during the study or is unable to continue the study, he / she will be excluded from the study.

Intervention groups

Fumaria Parviflora Capsule Group: This group takes one Fumaria Parviflora capsule daily for 8 weeks. Gabapentin capsule group: This group takes gabapentin capsules three times a week for up to 8 weeks.

Main outcome variables

pruritus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040049N5**

Registration date: **2020-11-15, 1399/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**

Update count: **0**

Registration date

2020-11-15, 1399/08/25

Registrant information

Name

Amirhosein Latifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3601

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-14, 1399/08/24

Expected recruitment end date

2021-02-12, 1399/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Fumaria Parviflora and Gabapentin in Treatment of Uremic Pruritus in Hemodialysis Patients

Public title

The effect of Fumaria Parviflora and Gabapentin on pruritus in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be on dialysis for at least six months Having pruritus for at least six weeks

Exclusion criteria:

Allergy to herbal medicines Lack of uremic pruritus

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a simple randomized clinical trial on dialysis patients with pruritus. In this study, people are divided into two groups of drugs and placebo. The method of assigning subjects to each group is that individuals are assigned every other one to one group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The two groups of drug and placebo receive very similar capsules, and they do not know the contents of the capsule. The statistical analyzer is not informed about the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.ARAKMU.REC.1399.042

Health conditions studied

1

Description of health condition studied

Dialysis patients

ICD-10 code

T81.502

ICD-10 code description

Unspecified complication of foreign body accidentally left in body following kidney dialysis

Primary outcomes

1

Description

Pruritus rate

Timepoint

One day before the intervention and one day after the intervention is measured

Method of measurement

Pruritus severity with Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" This group is given Fumaria officinalis capsules. Fumaria officinalis plant belongs to the anemone plant family. Total extract of this plant is used. The dose is 1500 mg / kg. Take one capsule after dinner for 8 weeks. This capsule is made by Shahid Beheshti University Pharmacy Department.

Category

Treatment - Drugs

2

Description

"Intervention group": This group is given gabapentin capsules. The dose is 300 mg / kg. For 8 weeks, take three capsules every week after dinner. This capsule is made by Raha Pharmaceutical Company of Isfahan.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Half-State Center for Supportive Dialysis in Arak(Hami)

Full name of responsible person

Nasser Saeedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Seied Amirhosein Latifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Internal Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable