Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
pruritis

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
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Name of organization / entity
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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
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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
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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