Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Comparison of Fumaria parviflora L. with placebo on treatment of refractive uremic pruritus of hemodialysis patients

Protocol summary

Summary

The main purpose of this study is to evaluate the effect of Fumaria Parviflora (FP) on treatment of uremic pruritus of hemodialysis patients. Design: a randomized double-blind placebo-controlled clinical trial. In this study 70 hemodialysis patients (older than 18 years old) with uremic pruritus more than 6 weeks and at least a course of antipruritic therapy without proper response will enroll. After proper informing patients and taking testimonial the patients will be divided in two groups randomly. One group will receive FP (2 capsules three times a day before mealtime for 8 weeks) and one group will receive placebo (2 capsules three times a day before mealtime for 8 weeks). pruritus severity will be assessed by VAS system and DUO questionnaire before and after treatment course and each week during the treatment course. PTH و Hb , BUN , Creatinin, Albumin, ALT, AST, ca, P, PTH, hsCRP, IFN gama , IL4 will be measured before and after treatment course too. Finally two groups will be compared according to changes in their scores of pruritus and the levels of IL4, hsCRP and IFN-gama .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080110410N2**
Registration date: **2015-09-18, 1394/06/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

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Name of organization / entity

Shiraz University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shiraz University of Medical Sciences

Expected recruitment start date

2015-09-26, 1394/07/04

Expected recruitment end date

2015-12-11, 1394/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Fumaria parviflora L. with placebo on treatment of refractive uremic pruritus of hemodialysis patients

Public title

Evaluation the effect of Fumaria Parviflora on treatment of hemodialysis patients pruritus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hemodialysis patients older than18 years old with itching more than 6 weeks; VAS score equal or more than 4; patients with hemodialysis twice or three times a week; patients should took at least a course of antipruritic treatment with no proper response.

Exclusion criteria: liver disease; respiratory disease; kt/V less than 1.2; convulsion history; any dermatologic disease that induce itching; hemolytic disease; malignancies; cholestasis; hepatitis B or C infection; presence of anemia with hemoglubin less than 10 .

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization will done according balance blocked randomization with four groups in each block.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand St.

City
Shiraz

Postal code

Approval date
2015-07-12, 1394/04/21

Ethics committee reference number
IR.SUMS.REC.1394.63

Health conditions studied

1

Description of health condition studied
uremic pruritus

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Duo score

Timepoint
before and after intervention and weekly during intervention period

Method of measurement
by questionnair and calculating score

2

Description
visual analogue scale

Timepoint
before and after intervention and weekly during intervention period

Method of measurement
visual analogue scale ruler

Secondary outcomes

1

Description
Interleukin4

Timepoint
Before and after intervention

Method of measurement
with Interleukin4 ELISA kit

2

Description
Interferon gama

Timepoint
Before and after intervention

Method of measurement
with Interferon gama ELISA Kit

3

Description
hsCRP

Timepoint
Before and after intervention

Method of measurement
with hsCRP ELISA kit

Intervention groups

1

Description
Intervention group: Fumaria Parviflora capsule produced by Shiraz School of Pharmacy, administer two capsules before breakfast, lunch and dinner (300 mg Fmaria Parviflora powder in each capsule) for 8 weeks.

Category
Treatment - Drugs

2

Description
Control group: Placebo capsule produced by Shiraz School of Pharmacy, administer two capsules before breakfast, lunch and dinner for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Haj Ebrahimi dialysis center
Full name of responsible person
Mr. Rasti
Street address
Sadra city
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Zand St.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty