

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 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, Hb, BUN, Creatinin, Albumin, ALT, AST, ca, P, PTH, hsCRP, IFN-gamma, 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-gamma.

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

Name

Rahimeh Akrami

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 than 18 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 hemoglobin 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 questionnaire 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

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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

Rahimeh Akrami

Position

M.D./PhD candidate of Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Name of organization / entity

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Other areas of specialty/work

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty