

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of Fumaria Parviflora L. on post burn pruritus: A randomized double- blind clinical trial

#### Protocol summary

##### Study aim

Fumaria parviflora L. and terminalia chebula Retz for treatment of post burn pruritus

##### Design

a double-blind, randomized controlled clinical trial with the parallel-groups design of 45 patients with Balance blocked randomization method

##### Settings and conduct

Burned patients with uncontrolled pruritus that come to Amir\_Almomenin clinic placed in A, B or C group according randomization table. Only pharmacist knows which one is case or control group. At first, questioner fills questionnaire and detect the severity of pruritus according VAS (visual analog scale). drugs are taken to patient for two weeks. after 2 weeks, severity of pruritus is evaluated and

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-patients with post burn pruritus 2-over 18 years old 3-VAS>=4 Exclusion criteria: 1-not having liver disease, kidney disease, respiratory disease, metabolic disease, hypertension, convulsion or skin diseases that lead to pruritus 2-not having a hemolytic disease

##### Intervention groups

Patients are placed in 3 groups. The groups take Fumaria parviflora L. or the combination of Fumaria parviflora L. and terminalia chebula Retz or flour.

##### Main outcome variables

severity of pruritus

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180609040016N2**

Registration date: **2020-10-07, 1399/07/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-07, 1399/07/16**

Update count: **0**

##### Registration date

2020-10-07, 1399/07/16

##### Registrant information

###### Name

Abdolkhalegh Keshavarzi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3614 6521

###### Email address

keshavarzg@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2020-11-20, 1399/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of Fumaria Parviflora L. on post burn pruritus: A randomized double- blind clinical trial

##### Public title

Evaluation the effect of Fumaria Parviflora L. on post burn pruritus

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

patients with post burn pruritus over 18 years old Visual Analogue Scale  $\geq 4$

**Exclusion criteria:**

not having liver disease, kidney disease, respiratory disease, metabolic disease, hypertension, convulsion, skin diseases that lead to pruritus not having hemolytic disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done according blocked randomization with three groups in each block and the block's arrangement is randomly according to Random number table And the allocation of treatment for patients is based on the final order of the blocks and the order of the groups within each block.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Only pharmacist knows which one is control and which one is placebo. they are packed in A, B, C. Then each patients is placed in one group according randomization table.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand Ave., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2019-10-26, 1398/08/04

**Ethics committee reference number**

IR.SUMS.REC.1398.962

**Health conditions studied**

**1**

**Description of health condition studied**

1. Evaluation the effect of Fumaria Parviflora L. on post burn prurits. 2.Evaluation the effect of combination of Fumaria Parviflora L. and Terminalia Chebula Retz on post burn prurits.

**ICD-10 code**

L29.8

**ICD-10 code description**

Other pruritus

**Primary outcomes**

**1**

**Description**

the severity of post burn pruritus

**Timepoint**

every two weeks

**Method of measurement**

Visual Analogue Scale that 0 means no itching and 10 means the most severe of itching

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention: 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 4 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention: Fumaria Parviflora and Terminalia Chebula Retz capsule produced by Shiraz School of Pharmacy, administer two capsules before breakfast, lunch and dinner (300 mg Fmaria Parviflora powder in each capsule) for 4 weeks. group:

**Category**

Treatment - Drugs

### 3

#### Description

Control group: Placebo capsule produced by Shiraz School of Pharmacy, administer two capsules before breakfast, lunch and dinner for 4 weeks.

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Amiralmomenin hospital

###### Full name of responsible person

Abdolkhalegh Keshavarzi

###### Street address

Sadra Blvd.

###### City

Shiraz

###### Province

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###### Postal code

7198754361

###### Phone

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###### Fax

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###### Email

rahimeh.akrami@yahoo.com

###### Web page address

<https://amiralmomeninbh.sums.ac.ir/>

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Full name of responsible person

Dr. Abbas Rezaian-zadeh

###### Street address

Zand street

###### City

shiraz

###### Province

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###### Phone

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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

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

Rahimeh Akrami

###### Position

General physician

###### Latest degree

Medical doctor

###### Other areas of specialty/work

General Practitioner

###### Street address

Sadra city, Amir Al-Momenin Hospital

###### City

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###### Province

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۷۱۳۳۶ - ۷۱۳۴۸

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Full name of responsible person

Abdolkhalegh Keshavarzi

###### Position

Associate professor

###### Latest degree

Specialist

###### Other areas of specialty/work

General Surgery

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**Web page address**<https://amiralmomeninbh.sums.ac.ir/>**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Rahimeh Akrami

**Position**

General physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**City**

shiraz

**Province**

Fars

**Postal code**

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**Phone**

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**Email**

rahimeh.akrami@yahoo.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**

Yes - There is 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

primary outcome measure

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

for research

**From where data/document is obtainable**

rahimeh.akrami@yahoo.com

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

Ethics committee reference number

**Comments**