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 o pruritus according VAS (visual analog scale). drugs are taken to patient for two weeks. after 2 weeks, severity o 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)

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+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>=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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Abbas Rezaian-zadeh
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Web page address
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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
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Other areas of specialty/work
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Person responsible for updating data

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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