

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of anti-pruritic effects of curcumin in treatment resistant burn patients

#### Protocol summary

##### Study aim

Evaluation of anti-pruritic effects of curcumin in treatment resistant burn patients

##### Design

Randomized controlled Clinical trial with parallel groups on 100 patients with burn pruritus .

##### Settings and conduct

This study will be conducted as a pilot study on 100 burn patients with refractory pruritus hospitalized in Sina Hospital of Tabriz University of Medical sciences after screening by inclusion and exclusion criteria

##### Participants/Inclusion and exclusion criteria

Age over 18 years ; Having itching after burn injury ; Ability to understand and sign consent form Other causes of pruritus including renal failure ; Pregnancy; presence of any chronic active, uncontrolled or severe inflammatory disease ( such as autoimmune diseases, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease) ;Breastfeeding ; involvement in other clinical trials ; malabsorption syndrome ; Bleeding disorders ( Including coagulopathies) or high risk for bleeding ;intake of a curcumin supplement or other supplements that affecting itching such as omega\_3 in the recent month ; Intolerance or allergy to curcumin ; Receiving drugs that have an effect on inflammatory factors ( such as corticosteroids or other immunosuppressive drugs, non-steroidal anti-inflammatory drugs, pentoxifylline) in the recent 6 weeks; Use of warfarin ; Abuse of alcohol and other substances that cause dependence.

##### Intervention groups

Intervention group (curcumin recipient) includes 50 patients who will receive two capsules of curcumin ( 40mg activing redient in each capsule ) daily by mouth for 3 months in addition to standard treatment of pruritus ( including antihistamines and gabaergic medications ). The control group included 50 patients who will be treated by mouth for 3 months to standard treatment of pruritus including antihistamines and

gabaergic medications .

##### Main outcome variables

Pruritus score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170609034406N7**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

##### Registration date

2021-05-14, 1400/02/24

##### Registrant information

##### Name

Afshin Gharekhani

##### Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 1315

##### Email address

gharekhanian@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of anti-pruritic effects of curcumin in treatment resistant burn patients

**Public title**  
anti-pruritic effects of curcumin on refractory burn itching

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age over 18 years ; Having itching after burn injury ; Ability to understand and sign consent form  
**Exclusion criteria:**  
Other causes of pruritus including renal failure ; Pregnancy; presence of any chronic active, uncontrolled or severe inflammatory disease ( such as autoimmune diseases, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease) ;Breastfeeding ; involvement in other clinical trials ; malabsorption syndrome ; Bleeding disorders ( Including coagulopathies) or high risk for bleeding ;intake of a curcumin supplement or other supplements that affecting itching such as omega\_3 in the recent month ; Intolerance or allergy to curcumin ; Receiving drugs that have an effect on inflammatory factors ( such as corticosteroids or other immunosuppressive drugs, non-steroidal anti-inflammatory drugs, pentoxifylline) in the recent 6 weeks; Use of warfarin ; Abuse of alcohol and other substances that cause dependence.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, Permuted Block Randomization method will be used for assigning patients into control and treatment groups. In this study, there will be 25 blocks containing 4 patients allocated to treatment and the control group. Random numbers in this study will be given using the Excel software to determine blocks and study groups randomly.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

##### Street address

Ardabil University of Medical Sciences complex , Daneshgah Square , End of Daneshgah street

##### City

Ardabil

##### Province

Ardabil

##### Postal code

8599156189

#### Approval date

2020-06-08, 1399/03/19

#### Ethics committee reference number

IR . ARUMS . REC . 1399.171

## Health conditions studied

### 1

#### Description of health condition studied

Burn pruritus

#### ICD-10 code

L29.8

#### ICD-10 code description

Other pruritus

## Primary outcomes

### 1

#### Description

pruritus score

#### Timepoint

Before starting the intervention, Six weeks after the intervention and at the end of the intervention period.

#### Method of measurement

Standard questionnaire

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before starting the intervention, Six weeks after the intervention and at the end of the intervention

#### Method of measurement

Standard questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Intervention group (curcumin recipient) includes 50 patients who will receive two capsules of curcumin ( 40mg activating redient in each capsule ) daily by mouth for 3 months in addition to standard treatment of pruritus ( including antihistamines and gabaergic medications )

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The control group included 50 patients who will be treated by mouth for 3 months to standard treatment of pruritus including antihistamines and gabaergic medications .

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina Haspital

##### Full name of responsible person

Afshin Gharekhani

##### Street address

Sina Educational and Medical Center, between Shahid Montazeri and Hafez intersections, Azadi Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5147663419

##### Phone

+98 41 3549 8342

##### Email

anqarekhani@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ardabil University of Medical Sciences

##### Full name of responsible person

Dr Mohammadhasan Pourrashid

##### Street address

Ardabil University of Medical Sciences complex ,  
Daneshgah Square , End of Daneshgah street

##### City

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##### Province

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##### Postal code

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##### Phone

+98 45 3352 2437

##### Fax

+98 45 3352 2197

##### Email

m.pourrashid@pharmacy.arums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Ardabil 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Afshin Gharekhani

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Faculty of Pharmacy , Tabriz University of Medical Science , Golgasht Street

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##### Phone

+98 41 3230 5351

##### Email

anqarekhani@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences  
**Full name of responsible person**  
Afshin Gharekhani  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Clinical Pharmacy  
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gharekhanian@tbzmed.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Laya Alirezaei  
**Position**  
Pharmacy Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Pharmacy  
**Street address**

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Science , Golgasht Street  
**City**  
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**Province**  
East Azarbaijan  
**Postal code**  
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**Phone**  
+98 41 3230 5351  
**Email**  
alirezaeilaya@gmail.com

## 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

There is no further information

### Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to  
make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to  
make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to  
make this available