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 (sach 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
gharekhania@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 effrcts 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 (sach 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 activing 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Mohammadhasan Pourrashid
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Ardabil University of Medical Sciences complex , Daneshgah Square , End of Daneshgah street
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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
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
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Latest degree
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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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Threre 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