

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation the effect of Punica granatum L. ointment in second degree burn wound healing

#### Protocol summary

##### Study aim

Use of therapeutic effect Punica granatum L. dressing in the healing of second degree burn wound

##### Design

A double-blind, randomized controlled clinical trial with parallel groups in third phase designed for 15 patients in each group with Balance blocked randomization method

##### Settings and conduct

The study is performed on burn patients admitted to Amir Al-Momenin Hospital in Shiraz. The patients are divided into groups A and B according to the random table. Creatinine, Blood Urea Nitrogen, Hemoglobin and Liver function test tests are taken before starting treatment. The burn wound is irrigated with sterile normal saline serum and then dressing. On days 1, 3, 7, 10, 13, 21 sent wound culture for evaluation the wound infection control, dressing changed once daily. (Until the wound appears pink, clear, without discharge and has granulation tissue and healing epithelium.) Patients are visited daily by a doctor and their wounds are evaluated. Dressings and procedures are similar, nurses and physicians are blind to the research design.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Burn hospitalized patients with body mass index greater than 18 and less than 25 with a burn case area of 5% or less that has not been burnt for more than one day and is due to contact with a heat source of flame or hot liquids. Not inclusion criteria: pregnancy, having skin diseases and skin allergies to herbal medicines, having underlying liver disease, kidney disease, respiratory disease, cardiovascular disease, malignancy, immune deficiency, poisoning, trauma, intubation and joint involvement.

##### Intervention groups

One group treated with Punica granatum L. ointment and one group treated with silver sulfadiazine ointment (standard medical treatment)

##### Main outcome variables

Repair time; Wound infection control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180609040016N4**

Registration date: **2021-06-05, 1400/03/15**

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

Last update: **2021-06-05, 1400/03/15**

Update count: **0**

##### Registration date

2021-06-05, 1400/03/15

##### 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

2021-05-15, 1400/02/25

##### Expected recruitment end date

2021-10-17, 1400/07/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of Punica granatum L. ointment in second degree burn wound healing

**Public title**

Evaluation the effect of Punica granatum L. ointment in burn wound

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients between 18 and 60 years old Burn case area 5% or less than 5% Less than one day burn passed Burn sources: flame or hot liquids Body mass index more than 18 and less than 25 Patients with second degree burn wound

**Exclusion criteria:**

Not having skin diseases and skin allergies to herbal medicines Not having hepatic, renal, respiratory or cardiovascular diseases Not having malignancy, immune deficiency, anemia, poisoning, Trauma, Diabetes mellitus, joint injury or involvement Not be pregnant

**Age**

From **18 years** old to **60 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: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done according blocked randomization with two groups in each block, so 15 blocks are needed. The block's arrangement is according to Random number table. If the number came even, AB block is selected and if the odd number came, BA block is selected. The drugs are packaged by the pharmacist in two groups as A and B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients are explained about Punica granatum L. ointment and all patients are informed and their details are recorded in the prepared questionnaire, but according to the type of dressing use; Punica granatum L. or silver sulfadiazine are blind, the method, form and appearance of the dressing are the same in both groups and is performed by two trained and specific nurses who are related to the blind research project. The wounds evaluated by a specialist doctor who does not know the type of dressing and is blind like a investigator.

**Placebo**

Not 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.

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2019-09-15, 1398/06/24

**Ethics committee reference number**

IR.SUMS.REC.1398.774

**Health conditions studied****1****Description of health condition studied**

Evaluation the effectiveness of Punica granatum L. in second degree burn wound healing

**ICD-10 code**

T21.2

**ICD-10 code description**

Burn of second degree of trunk

**Primary outcomes****1****Description**

Wound healing time

**Timepoint**

Daily once

**Method of measurement**

Inspection and Photographic stereology method

**2****Description**

Wound infection control

**Timepoint**

Days 1,3,7,10,13,21

**Method of measurement**

Wound Culture

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Hospitalized patients with second degree burn wound with an area of 5% or less, first irrigation with sterile normal saline and then dressing with the ointment of Punica granatum L. plant, made by Shiraz School of Pharmacy, as four grams per one percent of burn wound will be done. Ingredients included Dracaena cinnabri, Olive oil, Cerussa, Cinnamomum camphora, Punica granatum, Lithargyous and Honey wax.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: dressing with silver sulfadiazine ointment (standard medical treatment) manufactured by Sina Darou with the same method as the intervention group with four grams per one percent of burn wound

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Al-Momenin Hospital, Shiraz

##### 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

Keshavarzg@sums.ac.ir

##### 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

Abbas Rezaian-zadeh

#### Street address

Zand Street

#### City

Shiraz

#### Province

Fars

#### Postal code

14336 - 71348

#### Phone

+98 71 3230 5410

#### Email

Keshavarzg@sums.ac.ir

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Https://research.sums.ac.ir

#### 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

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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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**Person responsible for updating data****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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**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 research

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

For research

**From where data/document is obtainable**

[Keshavarzg@sums.ac.ir](mailto:Keshavarzg@sums.ac.ir)

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

Ethics committee reference number

**Comments**