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)

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+98 71 3614 6521

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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, Lithargyoum 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

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Abbas Rezaian-zadeh

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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

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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 research
Under which criteria data/document could be used
For research
From where data/document is obtainable
Keshavarzg@sums.ac.ir
What processes are involved for a request to access data/document
Ethics committee reference number
Comments