Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effectiveness of treatment Plantago major L. in second degree burn wound healing

Protocol summary

Study aim
Use of therapeutic effect Plantago major L. dressing in the healing of second degree burn wound

Design
A double-blind, randomized controlled clinical trial with parallel groups designed for 15 patients 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, BUN, Hb, Hct and LFT tests are taken before starting treatment. The burn wound is irrigated with sterile normal saline serum and then dressing. The patient's pain before and after dressing is measured based on Visual Analogue Scale. (10 most pain and 1 least) 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
Burn hospitalized patients with body mass index greater than 18 and less than 25 with a burn area of 5% or less and second degree that has not been burnt for more than one day and is due to contact with a heat source of flame or hot liquids , Are not pregnant and do not have skin diseases and skin allergies to herbal medicines and do not have underlying liver, kidney, respiratory, cardiovascular disease, malignancy, immune deficiency, poisoning, trauma, intubation and joint involvement.

Intervention groups
One group treated with Plantago major L.ointment and one group treated with silver sulfadiazine ointment (standard medical treatment)

Main outcome variables
Repair time; Pain relief; Wound infection control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180609040016N3**
Registration date: **2020-12-08, 1399/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-08, 1399/09/18**
Update count: **0**

Registration date
2020-12-08, 1399/09/18

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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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation the effectiveness of treatment Plantago major L. in second degree burn wound healing

Public title
Evaluation the effect of Plantago major L. in second degree burn wound healing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with second degree burn wound 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

Exclusion criteria:
Do not have skin diseases and skin allergies to herbal medicines Don't have hepatic, renal, respiratory or cardiovascular diseases Don't have malignancy, immune deficiency, anemia, poisoning, Trauma, Diabetes mellitus, joint injury or involvement. Don't have pregnancy

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by blocked randomization method with double blocks and the order of the blocks is random. Randomization of blocks is done using a table of random numbers 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
Patients are explained about Plantago major L. ointment and all patients are informed and their details are recorded in the prepared questionnaire, but according to the type of dressing use; Plantago major 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
2019-11-23, 1398/09/02

Ethics committee reference number
IR.SUMS.MED.REC.1398.473

Health conditions studied

1

Description of health condition studied
Evaluation the effectiveness of Plantago Major 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
Pain relief

Timepoint
Daily

Method of measurement
Visual Analogue Scale

3

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 irrigated with sterile normal saline and then with the dressing of Plantago major L. plant, made by Shiraz School of Pharmacy; The leaves of Plantago major L. plant are ground into a fine powder with a mill, then added with a ratio of 1/20 of sterile water and placed in a hotplate for three hours. After cooling, pass through a suitable filter and the extract is frozen and dried, then with a concentration of 10%. It is placed in Vaseline. Patients are dressed once a day until the wound heals.
Category
Treatment - Drugs

2

Description
Control group: dressing with silver sulfadiazine ointment (standard medical treatment) with the same method as the intervention group
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
Hossein Moradi Sarvestan
Position
Resident
Latest degree
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Other areas of specialty/work
General Surgery
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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