

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Email address

keshavarzg@sums.ac.ir

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

Medical doctor

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