

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

##### Phone

+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

**Street address**

Sadra Blvd.

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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**

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**Postal code**

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**Phone**

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**Web page address**

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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 scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Abdolkhalegh Keshavarzi  
**Position**  
Associated professor  
**Latest degree**  
Specialist  
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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**  
Associated professor

**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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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