

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Randomized clinical trial of standardized topical formula containing standard extracts of *Arnebia euchroma*, *Malva sylvestris* and sesame oil (less than 20%) vs. Silversulfadiazine cream on wound healing in 2nd degree burns

Protocol summary

Summary

Objectives: Wound healing properties(in 2nd degree burns) of a patented topical formula containing standard extracts of *Arnebia euchroma*, *Malva sylvestris* and sesame oil (less than 20%), formulated in Shiraz School of Pharmacy according to pharmacognostic and pharmaceutical standards will be compared with silver sulfadiazine(1%) in a single-blind randomized clinical trial. Design and setting conducts: A single-blind randomized clinical trial will be performed with two 25 persons groups after explanation the procedure for patients and filling out the informed consent forms by them. Participants including major eligibility criteria: Patients aged between 20-60 years old with 2nd degree burn wounds. Intervention: wounds will be dressed up with either silver sulfadiazine or our new formulated ointment according to randomization every other day. Data from wounds are reported by a physician and process of healing will be photographed until epithelialization of wounds. Main outcome measures (variables): The surface of wounds according planimetric method will be calculated and compared in two groups. Main outcome measures: Collected observations before and after intervention will be compared and data will be analyzed with SPSS and their comparison will be performed with T-test..

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203059204N1**

Registration date: **2014-04-28, 1393/02/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-28, 1393/02/08

Registrant information

Name

Azadeh Hamed

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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hamediaz@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-07-01, 1391/04/11

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of standardized topical formula containing standard extracts of *Arnebia euchroma*, *Malva sylvestris* and sesame oil (less than 20%) vs. Silversulfadiazine cream on wound healing in 2nd degree

burns

Public title

Randomized clinical trial of standardized topical formula containing standard extracts of Arnebia euchroma, Malva sylvestris and sesame oil (less than 20%) vs. Silversulfadiazine cream on wound healing in 2nd degree burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged between 20 to 60 years old; 2nd degree burn wounds; burn surface area up to 5% Exclusion criteria: Epilepsy; Diabetes; Cardiovascular diseases; pregnancy; Breast feeding; electrical and respiratory burns

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee, Shiraz University of Medical Sciences

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Ave., Shiraz, Iran

City

shiraz

Postal code

71345-1978

Approval date

2012-02-04, 1390/11/15

Ethics committee reference number

CT- 90 - 5935

Health conditions studied

1

Description of health condition studied

provides a standard herbal formulation to heal burn wounds

ICD-10 code

T21,T22,T2

ICD-10 code description

Burn and corrosion of trunk -Burn and corrosion of shoulder and upper limb -Burn and corrosion of wrist and hand -Burn and corrosion of hip and lower limb, except ankle and foot -Burn and corrosion of ankle and foot

Primary outcomes

1

Description

wound healing time

Timepoint

daily

Method of measurement

time between admission and epithelialization or preparation for skin graft

2

Description

surface area of wounds needed to be grafted

Timepoint

daily

Method of measurement

by ruller

Secondary outcomes

1

Description

allergy to applied treatment - infection

Timepoint

21day

Method of measurement

visit by expert physician

Intervention groups

1

Description

Intervention: Dressing with patented topical herbal formulation containing extracts of Arnebia euchroma, Malva sylvestris and sesame oil (less than 20%) after disinfection of wounds according to standard method every other day by responsible physician. According to patient conditions and wound types the treatment will last 1-3 weeks.

Category

Treatment - Drugs

2

Description

Control group: Dressing the wounds using silver sulfadiazine manufactured by Sobhan Pharmaceutical company after disinfection of wounds according to standard method every other day by physician in hospital and will last between 1 week to 3 weeks (depends on wound healing)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghotbedin burn Hospital

Full name of responsible person

Dr Ali Akbar Mohammadi

Street address

Ghotbedin burn Hospital, Fakhr abad street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali Poostforooshfard

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Ave., Shiraz, Iran

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Shiraz

Grant name

905935

Grant code / Reference number

905935

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Mohammadi

Position

Plastic Surgeon, Assistant Professor

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Azadeh Hamed; Dr Ali Akbar Mohammadi; Dr Gholamhossein Yousefi; Dr Alireza Salehi

Position

Ph D in Pharmacognosy; Plastic Surgeon; PhD in Pharmaceutics; MD in Epidemiology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Azadeh Hamed; Dr Ali Akbar Mohammadi

Position

Assistant professorin Pharmacognosy; Assistant
professorin Plastic Surgery

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty