Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Hamedi
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3242 4127
Email address
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

City
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
Shiraz Burn Research Center,Ghotbeddin Shirazi Hospital, Fakhr Abad st,Shiraz Shiraz

City
Shiraz

Postal code
54733-71638

Phone
+98 71 1820 8880

Fax
+98 71 1821 7090

Email
mohamadiaa@sums.ac.ir; burnres1@sums.ac.ir

Web page address
http://hburn.sums.ac.ir/connection/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Azadeh Hamedi; Dr Ali Akbar Mohammadi; Dr Gholamhossein Yousefi; Dr Alireza Salehi

Position
Ph D in Pharmacognosy; Plastic Sergeon; PhD in Pharmaceutics; MD in Epidemiology

Other areas of specialty/work

Street address
Shiraz Burn Research Center,Ghotbeddin Shirazi Hospital, Fakhr Abad street,Shiraz, Iran

City
Shiraz

Postal code
71638-54733

Phone
+98 71 1821 9638

Fax
+98 917 113 3639

Email
hamediaz@sums.ac.ir; mohamadiaa@sums.ac.ir; ghyousefy@yahoo.com; salehialireza45@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Azadeh Hamedi; Dr Ali Akbar Mohammdi

Position
Assistant professorin Pharmacognosy; Assistant professorin Plastic Surgery
Other areas of specialty/work
Street address
Shiraz Burn Research Center,Ghotbeddin Shirazi Hospital, Fakhr Abad street,Shiraz
City
Shiraz
Postal code
71638-54733
Phone
+98 71 1821 9638
Fax
+98 917 113 3639
Email
hamediaz@sums.ac.ir; mohamadiaa@sums.ac.ir
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