Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Comparison of the effect of hydroalcoholic extract gel of Arnebia euchroma and Silver Sulfadiazin and Alpha ointments on wound healing in patients with heat-induced superficial skin wounds

Protocol summary

Summary

The aim of the present study is to investigate the healing effects of Arnebia euchroma extract gel on heat-induced skin wounds and compare it with commonly prescribed topical agents namely silver sulfadiazine ointment and Alpha ointment. Patients with skin wounds with less than 2 square-centimeters surface which are induced by heat or burn will be included after giving informed consents and will be divided into five groups of 300 individuals. Groups 1 to 5 will receive Silver Sulfadiazine ointment, Alpha ointment, Arnebia euchroma 5% gel, Arnebia euchroma 10% gel, and Arnebia euchroma 20% gel, respectively, twice daily till complete reepithelization of the wound surface. Participants have the right to leave at any time during the study. Those who show any adverse effects or reaction regarding their treatment or show inadequate wound healing will be excluded to receive another proper treatment. At the end wounds will be evaluated for any scar formation, infection, and duration of reepithelization and wound closure rate.

General information

Acronym

AETRIAL

IRCT registration information

IRCT registration number: **IRCT2013102115102N1**
Registration date: **2014-02-11, 1392/11/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-11, 1392/11/22

Registrant information

Name

Soheil Ashkani-Esfahani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1626 2033

Email address

ashkanis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Shiraz, Iran

Expected recruitment start date

2014-01-03, 1392/10/13

Expected recruitment end date

2014-09-30, 1393/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of hydroalcoholic extract gel of Arnebia euchroma and Silver Sulfadiazin and Alpha ointments on wound healing in patients with heat-induced superficial skin wounds

Public title

The effect of an herbal extract (Arnebia euchroma) for wound healing

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having wounds with 2cm area or less; Having no other systemic diseases affecting the wound

healing process; Having no other dermatological diseases; Filling informed consent and participating in using the prescribed drugs; Having wounds caused by traumatic injuries or burns Exclusion criteria:Having wounds sized more than 2 cm; Having any systemic diseases or dermatological diseases; Willing to leave the study at any time during the treatment; Having wounds caused by any other reasons than traumatic injury or burns

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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
Karim Khan Zand St, Shiraz Medical school

City
Shiraz

Postal code
0

Approval date
2013-12-29, 1392/10/08

Ethics committee reference number
92-01-21-6743

Health conditions studied

1

Description of health condition studied
heat-induced Skin wounds

ICD-10 code
T30.1

ICD-10 code description
Burn of first degree, body region unspecified

2

Description of health condition studied
heat-induced skin wounds

ICD-10 code
T30.2

ICD-10 code description
Burn of second degree, body region unspecified

3

Description of health condition studied
Heat-induced skin wounds

ICD-10 code
T31.0

ICD-10 code description
Burns involving less than 10% of body surface

Primary outcomes

1

Description
wound closure rate

Timepoint
at the begining of the study and then daily till the closure of the wound

Method of measurement
ruler

Secondary outcomes

1

Description
Scar formation

Timepoint
at the end

Method of measurement
observation

2

Description
wound infection

Timepoint
during and at the end of the study

Method of measurement
Culture

Intervention groups

1

Description
Group E5: patients were treated with Arnebia euchroma gel 20% twice daily for 28 days. The gel covered the wound properly then dressed with bandages in the

standard method.

Category

Treatment - Drugs

2

Description

Group E3: patients are treated with Arnebia euchroma gel 5% twice daily for 28 days. The gel covere the wound properly then dresse with bandages in the standard method.

Category

Treatment - Drugs

3

Description

Group P3: patients are treated with Arnebia euchroma gel 20% twice daily for 28 days. The gel covere the wound properly then dresse with bandages in the standard method.

Category

Treatment - Drugs

4

Description

Group E4: patients are treated with Arnebia euchroma gel 10% twice daily for 28 days. The gel covere the wound properly then dresse with bandages in the standard method.

Category

Treatment - Drugs

5

Description

Group P2: patients are treated with Arnebia euchroma gel 10% twice daily for 28 days. The gel covere the wound properly then dresse with bandages in the standard method

Category

Treatment - Drugs

6

Description

Group E1: patients are treated with Silver sulfadiazine ointment twice daily for 28 days. The ointment covere the wound properly then dresse with bandages in the standard method.

Category

Treatment - Drugs

7

Description

Group E2: patients are treated with Alpha ointment twice daily for 28 days. The ointment covere the wound properly then dress with bandages in the standard method.

Category

Treatment - Drugs

8

Description

Group P1: patients are treated with Arnebia euchroma gel 5% twice daily for 28 days. The gel cover the wound properly then dress with bandages in the standard method.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital of Shiraz University of Medical Sciences

Full name of responsible person

Soheil Ashkani Esfahani

Street address

Student Research Committee, Shiraz Medical School, Karimkhan Zand St

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

SadraTech Company

Full name of responsible person

AliAsghar Karimi

Street address

Farahmandfar hospital, Ghasredasht St

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

SadraTech Company

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

Soheil Ashkani Esfahani

Position

Medical Student (intern), The Secretary of Student Research Committee

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

Ethics Committee of Shiraz University of Medical School

Full name of responsible person

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MD, Deputy President of Ethics Committee

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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