

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of herbal root of the Arnebia euchroma ointment and silver sulfadiazine on second degree burn wound

Protocol summary

Summary

The design of this study is a single blind clinical trial. The aim of the study is to evaluate the effect of the herbal roots of the Arnebia euchroma ointment(AE) dressing and silver sulfadiazine(SSD) dressing on wound healing in burn patients. After getting informed consent, 30 patients will be participating in the emergency department of the Sari Zare burn hospital. The side of the patient's burns are randomly assigned to the AE ointment or SSD cream treatment. Inclusion criteria: Men and women aged 16 to 65 years; bilateral and similar depth second degree burn wound in two different sides of the body. Exclusion criteria: pregnant women; Patients who have a serious disease of the liver, heart, kidney; diabetic patients; skin sensitivity and no willingness to participate in this study. After primary care of the wound, One side of the body will be treated with Arnebia euchroma ointment and the opposite site will be treated with routine method (silver sulfadiazine cream). The size of the wound will measure by the photography and ruler every two days. Wound area and percentage of wound contraction, healing time will be evaluated. Clinical assessment of recovery such as itching, bleeding, redness, pain, burning and infection will be blind evaluated during dressing by expert physician and nurse.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412154492N2**

Registration date: **2015-02-23, 1393/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

Ebrahim Nasiri formi

Name of organization / entity

Mazansdaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of research, Mazandaran University of Medical Sciences

Expected recruitment start date

2014-12-16, 1393/09/25

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of herbal root of the Arnebia euchroma ointment and silver sulfadiazine on second degree burn wound

Public title

The effect of herbal root of the Arnebia euchroma ointment on second degree burn wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: bilateral second degree burn wound; aged 16 to 65 years. Exclusion criteria: pregnant women;

existing of systemic disease such as diabetic patients; Cardiovascular disease; hypertension; Renal failure; Skin sensitivity; no willingness to participate.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

Deputy of research of Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

4847144718

Approval date

2012-08-20, 1391/05/30

Ethics committee reference number

2504/4/ - 09/09/93

Health conditions studied

1

Description of health condition studied

Burn and corrosion of head and neck

ICD-10 code

T20.2

ICD-10 code description

Burn of second degree of head and neck

2

Description of health condition studied

Burn and corrosion of trunk

ICD-10 code

T21.2

ICD-10 code description

Burn of second degree of trunk

3

Description of health condition studied

Burn and corrosion of shoulder and upper limb

ICD-10 code

T22.2

ICD-10 code description

Burn of second degree of shoulder and upper limb

4

Description of health condition studied

Burn and corrosion of wrist and hand

ICD-10 code

T23.2

ICD-10 code description

Burn of second degree of wrist and hand

5

Description of health condition studied

Burn and corrosion of hip and lower limb

ICD-10 code

T24.2

ICD-10 code description

Burn of second degree of hip and lower limb

6

Description of health condition studied

Burn and corrosion of ankle and foot

ICD-10 code

T25.2

ICD-10 code description

Burn of second degree of ankle and foot

Primary outcomes

1

Description

Wound size

Timepoint

First day of burn injury; The third day; The fifth day; The seventh day; The tenth day; The twelfth day; The fifteenth day; The twentieth day; Twenty- fifth day; The thirtieth day

Method of measurement

By photograph and ruler

Secondary outcomes

1

Description

Infection

Timepoint

daily

Method of measurement

observation

2

Description

Pain

Timepoint

daily

Method of measurement

VAS scale

3

Description

Itching

Timepoint

daily

Method of measurement

Visual analog scale

4

Description

secretion

Timepoint

during daily dressing

Method of measurement

Observation

5

Description

Inflammation

Timepoint

daily

Method of measurement

Observation

6

Description

Redness

Timepoint

daily

Method of measurement

observation

7

Description

Burning

Timepoint

daily during dressing

Method of measurement

Visual analoge Scale

8

Description

percentage wound contraction

Timepoint

each two days

Method of measurement

photography and ruler

Intervention groups

1

Description

A burned patient will be treated daily with tiny layer of the Arnebia euchroma ointment 10% on one part of the wound area. This process will be continued to complete of wound healing.

Category

Treatment - Drugs

2

Description

A burned patient will be treated daily with tiny layer of Silver sulfadiazine 1% on the second part of the wound are. This process will be continued to complete of wound healing.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Burn hospital of Zare, 5 th kilometer, Neka- Sari road.

Full name of responsible person

Ebrahim Nasiri

Street address

Zare psychiatry and burn center, 5 th kilometer, Neka- Sari road, Mazandaran University of Medical Sciences

City

Sari

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ravanbkhsh Esmaeili

Street address

Moallem Square, Deputy of research of Mazandaran University of Medical Sciences

City

Sari

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mazandaran 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

research center, Mazandaran University of medical sciences

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Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Sayed Jalal Hosseinimehr

Position
Ph.D professor

Other areas of specialty/work

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Dr Sayed Jalal Hosseinimehr

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Professor of radiopharmacy

Other areas of specialty/work

Street address
Faculty of Pharmacy+ Traditional and Complementary

Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
Faculty member of Mazandaran University of Medical Sciences and Ph.D candidate of Traditional and complementary

Other areas of specialty/work

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Fax

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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