Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
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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

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
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Dr Sayed Jalal Hosseinimehr
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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