Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of therapeutic effects of the herbad Zofa ointment with Silversulfadiazin in burning therapy

Protocol summary

Summary

The objective of randomized, double-blind, placebo-controlled study was to compare therapeutic effects of herbal Zofa ointment with Silversulfadiazin in burning therapy. Inclusion criteria are hospitalized second degree burn patients who accept to participate in the study. Exclusion criteria are children; people without consciousness or with mental disability; the elderly; pregnant women; immunocompromised patients; patients with drug sensitivity history. In this study, 20 second degree burn patients in the burn ward of Sina hospital that are willing to participate in the study are selected randomly. A double-blinded treatment of Herbal Zofa ointment and topical silversulfadiazine will be applied thrice daily on two second degree burns on each patient for the duration of two months. Physical examination by a dermatologist is performed after each application of the treatment measures. Photos are taken at the beginning and end of the treatment, mid-process if necessary, to compare the effects of the two drugs in terms of patients' recovery. The patient will undergo a recorded verbal questionnaire in regards to side effects, efficiency of treatment and recovery for the two individual treatments. This will continue periodically for two months. The primary outcome is pain and irritation, erythema and secondary outcome is the healing and less pain of wound.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705119844N5**
Registration date: **2017-05-24, 1396/03/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

Name
Mehdi Amirnia
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of the herbad Zofa ointment with Silversulfadiazin in burning therapy

Public title

effects of the herbad Zofa ointment in burning therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: second degree burn patients

hospitalized; patients who decline to participate in research. exclusion criteria: the children; people without consciousness or mental disability; the elderly; pregnant women; immunocompromised patients; patients with drug sensitivity history.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Tabriz University of Medical Sciences

Street address
Third floor, Central Building, Tabriz University of Medical Sciences, Gholgasht ave, Tabriz, Iran

City
Tabriz

Postal code
5163639888

Approval date
2014-08-04, 1393/05/13

Ethics committee reference number
IR.TBZMED.REC.1393.9383

Health conditions studied

1

Description of health condition studied
burns

ICD-10 code
T22.2

ICD-10 code description
Burn of second degree of shoulder and upper limb, except wrist and hand

Primary outcomes

1

Description
Pain

Timepoint
Before the study, two months after the study.

Method of measurement
VAS Scale

Secondary outcomes

1

Description
Wound healing

Timepoint
Before the study, two months after the study

Method of measurement
Clinical examination

Intervention groups

1

Description
Control group: silver sulfadiazine, topical ointment, three times in a day for two months.

Category
Treatment - Drugs

2

Description
Case group: Zofa, herbal topical ointment, three times in a day for two months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
burn ward of Sina hospital

Full name of responsible person
Dr Arman Javan Rozeghar

Street address
Tabriz University of Medical Sceince

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chanscellor for research, Tabriz University of

Medical Sciences

Full name of responsible person

Hassan Soleimanpour

Street address

Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, East Azarbayjan, Iran

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chanscellor for research, Tabriz 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

Tabriz University of Medical Sceince

Full name of responsible person

Dr Arman Javan Rozeghar

Position

Dermatology Assistant

Other areas of specialty/work

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Dermatology Assistant

Other areas of specialty/work

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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