

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1540 6612

###### Email address

amirniyam@tbzmed.ac.ir

##### 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 Science

**City**

Tabriz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor 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 chancellor 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 Science

**Full name of responsible person**

Dr Arman Javan Rozeghar

**Position**

Dermatology Assistant

**Other areas of specialty/work**

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dermatologist

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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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*