

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Clinical Study the Effect of Zoush in Comperhansive Sulfadiazine 1 Ointment on Second-degree Burned Wound Healing

#### Protocol summary

##### Study aim

Comparative study of Zoush herbal ointment and silver sulfadiazine ointment in the healing and treatment of grade 2 burn wounds

##### Design

To perform the phase of a clinical trial: A non-randomized, non placebo and not controlled, study of 30 healthy volunteers with major inclusion criteria.

##### Settings and conduct

To apply herbal ointment, the upper extremities of volunteers in the anterior region of the right or left forearm from the elbow to the wrist joint will be selected as impregnated with a 5 mm thick herbal ointment. The impregnation site is first rinsed with 0.9% normal saline and the dressing will be applied after the use of the ointment. At all stages of treatment, before the daily dressing of the area used, sensitivity and potential infection and any adverse reactions will be assessed. Blood samples were taken from 30 volunteers before and at the end of the intervention, and serum and urea and creatinine enzymes (ALP-AST-ALT) were measured and compared before and after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy male or female volunteers aged 20-50 years old, without underlying disease such as diabetes; immune deficiency and skin problems; not using cigarettes and alcohol; willing to participate in research and able also to answer questions. Exclusion criteria in the first phase: any skin allergies to ointment and causing infection and fever; pain in the area of Zoush ointment; unwillingness to cooperate.

##### Intervention groups

A group of 30 healthy volunteers.

##### Main outcome variables

If the herbal ointment did not show any side effects, such as skin allergy and infection, as well as changes in liver enzymes and renal excretion samples before and after intervention in the blood serum of volunteers, then the next phase of clinical study would be performed on burn

patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200301046653N1**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

##### Registration date

2020-04-10, 1399/01/22

##### Registrant information

##### Name

mehdi nazari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3680 4015

##### Email address

nazarimahdi90@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Clinical Study the Effect of Zoush in Comprehensive Sulfadiazine 1 Ointment on Second-degree Burned Wound Healing

### Public title

Effect of Zoush herbal ointment in burn treatment

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy female or male volunteers aged 20 to 50 years old Be willing to participate in research and be able to answer questions Has read and signed the informed consent form

#### Exclusion criteria:

Have underlying illnesses such as diabetes and immune deficiencies such as cancer, AIDS Have severe skin allergies and skin problems People who use cigarettes and alcohol

### Age

From **20 years** old to **50 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

##### Street address

Unit 3, No. 50, Next to East Laleh First Health Park, Boulevard Imam Khomeini, Ferdis, Karaj

##### City

karaj

##### Province

Alborz

### Postal code

3143843711

### Approval date

2020-03-04, 1398/12/14

### Ethics committee reference number

IR.ABZUMS.REC.1398,252

## Health conditions studied

### 1

#### Description of health condition studied

Second-degree Burned Wound

#### ICD-10 code

T23.2

#### ICD-10 code description

Burn of second degree of wrist and hand

## Primary outcomes

### 1

#### Description

The size of the wound includes the depth and edge of the wound and the extent of the wound

#### Timepoint

Study days 7, 14 and 21

#### Method of measurement

BATES JENSIN Wound Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: in order to prepare the ointment of safflower herbs, thyme, Shiraz, oregano is purchased from the Barij essential oils and alcoholic extract. Finally, the extracts are powdered from the same company. The constituents of the extracts were measured using gas chromatography. The extracts are dissolved in a ratio of 1/3 in dimethyl sulfoxide. Honey is dissolved in distilled water in a ratio of 1/3. Polyurethane is dissolved in 6 m urea at a ratio of 1/3 and then subjected to indirect heat to evaporate urea. Extracts of Khuzestani, Thyme, and Oregano soluble, DMSO water-soluble honey and polyurethane soluble in urea are mixed in a separate falcon in a ratio of one to one and used as the primary stack of zush ointment compounds in other stages. Will take. Zucchini ointment will be used daily for 21 days.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Madani Hospital

**Full name of responsible person**

Mehdi Nazari

**Street address**

Unit 3, No. 50, Next to East Laleh First Health Park  
, Boulevard Imam Khomeini, Ferdis, karaj

**City**

karaj

**Province**

Alborz

**Postal code**

3143843711

**Phone**

+98 26 3680 4015

**Email**

nazarimahdi90@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohammad Nouri Sepehr

**Street address**

Deputy of Research and Technology., Saffarian Alley.,  
45 meters from Golshahr., Karaj Town.

**City**

karaj

**Province**

Alborz

**Postal code**

3143843711

**Phone**

+98 26 3464 3774

**Email**

dr.noorisepehr@abzums.ac.ir

**Web page address**

<https://abzums.ac.ir>

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

Yes

**Title of funding source**

Karaj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

### Person responsible for general inquiries

**Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mehdi Nazari

**Position**

Master s dedree not science Committee

**Latest degree**

Master

**Other areas of specialty/work**

histology

**Street address**

Unit 3, No. 50, Next to East Laleh First Health Park,  
Boulevard Imam Khomeini, Ferdis

**City**

Karaj

**Province**

Alborz

**Postal code**

3143843711

**Phone**

+98 26 3680 4015

**Email**

nazarimahdi90@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Leila Haj Maghsoudi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

**Street address**

Burn Clinic, Madani Hospital, Madani Square,  
Jahanshahr, Karaj Town

**City**

Karaj

**Province**

Alborz

**Postal code**

11111111111111

**Phone**

+98 26 3680 4015

**Email**

L.hajimaghsoudi@gmail.com

### Person responsible for updating data

**Contact****Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mehdi Nazari

**Position**

Master s dedree not science Committee

**Latest degree**

Master

**Other areas of specialty/work**

Anatomy

**Street address**

Unit 3, No. 50, Next to East Laleh First Health Park,  
Boulevard Imam Khomeini, Ferdis

**City**

karaj

**Province**

Alborz

**Postal code**

3143843711

**Phone**

+98 26 3680 4015

**Email**

nazarimahdi90@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Information about the results and data of the study subjects can be shared.

**When the data will become available and for how long**

The access period begins 6 months after the results are published.

**To whom data/document is available**

Data will be available only to researchers working in universities.

**Under which criteria data/document could be used**

Data recipients can only read and reference the article. And any misuse of the results is subject to prosecution as the drug formulation is patented.

**From where data/document is obtainable**

Applicants may request to receive study data by emailing the principal investigator nazarimahdi90@gmail.com and phone number 09126474345

**What processes are involved for a request to access data/document**

After receiving the email from the Principal Investigator, the data will eventually be sent to the applicant's workplace at the relevant medical university within 30 working days.

**Comments**

Given that this research project has been the result of an effort in the animal phase since 1993, it is only possible to use the data from the clinical trial of this study in compliance with existing rules and regulations.