

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
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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

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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

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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

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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

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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.