

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of ZOUSH in second degree burn wound healing in terms of histopathology and changes in the expression of some genes involved in wound healing process

Protocol summary

Study aim

This study is performed to evaluate the effect of local, inexpensive, standard and effective ZOUSH drug on the healing of second degree burn wounds through macroscopic and microscopic examination (histopathological) of the samples and to investigate the changes in the expression level of genes involved in this repair.

Design

Clinical trials are conducted in parallel, In this study, the case and control are both the same patient. The study is a one-way blind and phase 3 and is randomized in the sampling area. Excel function rand function is used for randomization.

Settings and conduct

This study is performed in Shahid Motahari Hospital. Sampling of each patient in the burn area is done before and after treatment. In this study, the patient, pathologist and geneticist were blinded. The patient is unaware of the type of treatment in the treated areas and the pathologist and geneticist have been blinded to the type of sample received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the presence of second degree burns in the patient referred to Shahid Motahari Hospital; their willingness to participate in the study; complete the informed consent form. Exclusion criteria: patients' unwillingness to participate in the study; the presence of first or third degree burns, a history of trauma or previous burns in the burned area; facial burns, which are aesthetically important.

Intervention groups

In this study, 20 patients are sampled in three areas. Due to pre-treatment sampling, after treatment in the ZOUSH-treated area and in the amniotic-treated area, each patient can be considered as a control for himself.

Main outcome variables

One of the goals of the Trauma Research Center is to find new and local treatments for burn trauma. In this project, a cheap and effective local medicine for the treatment of burn wounds will be genetically and histopathologically examined.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200731048258N1**

Registration date: **2020-10-22, 1399/08/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-22, 1399/08/01**

Update count: **0**

Registration date

2020-10-22, 1399/08/01

Registrant information

Name

Mohammad Soleymani Farsani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6614 5482

Email address

soleymani.mm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of ZOUSH in second degree burn wound healing in terms of histopathology and changes in the expression of some genes involved in wound healing process

Public title

Evaluation of the effectiveness of ZOUSH in burn wound healling

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

second degree burn wound

Exclusion criteria:

Burn wounds in aesthetically sensitive areas A history of previous trauma or burns to the burned area Patients' reluctance

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **3**

A 3mm tissue sample is taken from the burn patient's skin before treatment. a 3mm tissue sample will be taken in the area treated with ZOUSH and another 3mm tissue sample in the area of the amniotic dressing after treatment.

Randomization (investigator's opinion)

Randomized

Randomization description

A small portion of the patient's wound is randomly selected and treated with ZOUSH. The rest of the wound is treated with standard amniotic dressing. By accident, here means that the burn is not intended for a specific area of the body. In addition, a special part of the burned area is not considered. If there is a random burn in each organ, a part of it will be selected for treatment with ZOUSH.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, pathologist, and genetic researcher are completely unaware of which area is receiving standard amniotic fluid treatment and which area is being treated

with ZOUSH, and data analysis is performed by blinding.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

No. 9, Majd Alley, North Kargar Street, Enghelab Square, Tehran

City

Tehran

Province

Tehran

Postal code

1418945398

Approval date

2020-06-08, 1399/03/19

Ethics committee reference number

IR.BMSU.REC.1399.217

Health conditions studied**1****Description of health condition studied**

Second degree burn wounds

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of ZOUSH ointment on the healing of second degree burn wounds

Timepoint

Evaluation of genetic and histopathological changes before and after treatment with ZOUSH and standard amniotic dressing

Method of measurement

3 mm skin punch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Part of the burn patient's skin is treated with ZOUSH ointment. This ointment contains Satureja khuzestanica, Zataria multiflora and MenthaMozaffariani Jamzad with Honey, and Polyurethane. Used once on the burn and after seven days the effectiveness of the drug will be evaluated.

Category

Treatment - Drugs

2

Description

Intervention group: Part of the patient's skin is treated with a standard amniotic dressing. Sampling of this part is done on the seventh day after treatment to evaluate the effectiveness of treatment.

Category

Treatment - Drugs

3

Description

Control group: A portion of the patient's skin is biopsied and studied as a control before starting treatment. In this study, the case and control is the patient and its different parts of the skin before and after the treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid-Motahari-Hospital

Full name of responsible person

محمد سلیمانی فارسانی

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No. 9, Majd Alley, North Kargar Street, Enghelab Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

mohammad soleimani farsani

Position

specialist

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

At the end of the study, the results of the research will be publish as an article.

When the data will become available and for how long

data will be available endless.

To whom data/document is available

all people.

Under which criteria data/document could be used

in order to extend information in the fields of burn patients treatment the results will be available without limitations.

From where data/document is obtainable

paper publisher site.

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

one month later the request will be answered by the email.

Comments