

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

##### Street address

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

##### City

Tehran

##### Province

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##### Postal code

1418945398

##### Phone

+98 21 6657 0590

##### Email

soleymani.mm@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

محمد سلیمانی فارسانی

#### Street address

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#### City

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#### Province

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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

General Surgery

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North Kargar

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

محمد سلیمانی فارسانی

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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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)**

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 published 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**