

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Determination of the effectiveness of proderm herbal ointment in comparison with nitrofurazone cream in second degree burn wounds

#### Protocol summary

##### Study aim

Comparison of the effect of Arnebia euchrooma extract with nitrofurazone ointment on wound healing in second and burn patients

##### Design

In this study, 60 patients with second and third degree burns admitted to Ardabil University of Medical Sciences burn hospital were selected. Randomly divided into intervention and control groups and each participant is assigned a code.

##### Settings and conduct

Patients with second burns referred to Ardebil University of Medical Sciences burn hospital were selected through a single blinded study that participants in this study were not aware of the type of drug used.

##### Participants/Inclusion and exclusion criteria

Having a second or third degree burn wound; The shape of the burn wound is almost oval; general good; Exclusion criteria: A history of autoimmune diseases; HIV; A history of immunosuppressive drugs; A history of psychiatric disorders such as paranoid; A history of psychiatric hospitalization.

##### Intervention groups

Control group 1: Patients with second burns who will receive 0.2% nitrofurazone cream. Intervention group 1: Patients with second burns who will receive ointment containing proderm extract.

##### Main outcome variables

Evaluation and comparison of wound size using caliper and wound healing using wound photography on days 6, 12, 18 and 24 after treatment between the control and intervention groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200104045995N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

##### Registration date

2021-02-01, 1399/11/13

##### Registrant information

###### Name

Mohammad Vakili

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3326 1600

###### Email address

mohammad.vakili@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determination of the effectiveness of proderm herbal ointment in comparison with nitrofurazone cream in second degree burn wounds

##### Public title

Effect of Ventilation on Burn Healing

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having a second degree burn wound The shape of the burn wound is almost oval and regular Burn with boiling water, fire and acid.

### Exclusion criteria:

Having an underlying disease such as epilepsy Having a history of autoimmune diseases; Getting HIV History of taking immunosuppressive drugs History of psychotic disorder such as paranoid Hospitalization history in the psychiatric ward

## Age

From **2 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this method, the number of people assigned to each group is usually equal. In this method, blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as controls. The main goal of this method is to balance the number of participants in each group.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

##### Street address

Daneshgah St. Daneshgah

##### City

ardebil

##### Province

Ardabil

##### Postal code

5618985991

## Approval date

2020-08-03, 1399/05/13

## Ethics committee reference number

IR.ARUMS.REC.1399.280

## Health conditions studied

### 1

#### Description of health condition studied

Patients with second-degree burns

#### ICD-10 code

T29.2

#### ICD-10 code description

Burns of multiple regions, no more than second-degree burns mentioned

## Primary outcomes

### 1

#### Description

Wound size

#### Timepoint

The first day and every other day until the wound is completely healed

#### Method of measurement

To mm using calipers

## Secondary outcomes

### 1

#### Description

Wound healing rate

#### Timepoint

The first day and every other day until the wound is completely healed

#### Method of measurement

Wound imaging

## Intervention groups

### 1

#### Description

The effect of a patented topical formulation containing standardized extracts of the medicinal plant Hawachobeh, castor oil and olive oil formulated in Danesh Banain Andisheh Sabalan Health Company and in healing wounds caused by second degree burns in comparison with nitrofurazone cream will be investigated. In such a way that two types of treatments include 1- use of nitrofurazone cream on second degree burns 2- use of proderm ointment on second degree burns that in both treatments of the burn site (hands, feet and face) cause and type of burn are common. The statistical population for each group of 30 people in the age range of 2 to 50 years of those referred to the burn ward of Fatemi Hospital who have burns on similar limbs (in terms of organ and burn site) and those who have burns on the back and abdomen They will be removed.

Consumption of prodermal drug 2-3 mm in the burn site after washing with standard serum is applied topically on the wound once a day with sterile gas.

**Category**

Treatment - Drugs

**2****Description**

Control group: Patients with second-degree burns for whom nitrofurazone cream will be used daily

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

urn ward of Fatemi Hospital, Ardabil University of Medical Sciences

**Full name of responsible person**

mohamad vakili

**Street address**

amam

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

Ardabil University of Medical Sciences

**Full name of responsible person**

farhad pourfarzi

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info@arums.ac.ir

**Web page address**

<http://arums.ac.ir>

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

Yes

**Title of funding source**

Ardabil University of Medical Sciences

**Proportion provided by this source**

50

**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

**2****Sponsor****Name of organization / entity**

شرکت اندیشه سلامت سیلان

**Full name of responsible person**

siyamak mohamadi

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savalanm452@gmail.com

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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**

شرکت اندیشه سلامت سیلان

**Proportion provided by this source**

50

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

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

Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Ardabil University of Medical Sciences

**Full name of responsible person**  
Mohamad vakili

**Position**  
Specialty

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
General Surgery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Andishe Salamat Sabalan Co

## Full name of responsible person

Hamed arastegi

**Position**  
Expert

**Latest degree**  
Master

**Other areas of specialty/work**  
Medicinal Plants

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be 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

All data includes the primary and secondary consequences that can be shared.

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

6 months after printing the results.

### To whom data/document is available

Our data will only be available to researchers working in academia and academia.

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

Our data will be available to researchers working in academic and scientific institutions.

### From where data/document is obtainable

Hamed Arastegi provides data to applicants via email hamedaraz69@gmail.com.

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

Collecting patients and performing practical procedures for ten months, collecting data for one month, analyzing statistical data for one month, publishing information in the form of a six-month article.

### Comments

