

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

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۴۷۳۳۷۷۵

Phone

+98 45 3323 9033

Fax

+98 45 3323 2670

Email

fatemi@arums.ac.ir

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

Ardabil University of Medical Sciences

Full name of responsible person

farhad pourfarzi

Street address

daneshgah

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹۸۵۹۹۱

Phone

+98 45 3353 4790

Fax

+98 45 3353 4773

Email

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

Street address

Dastqeib

City

Ardabil

Province

Ardabil

Postal code

5613786179

Phone

+98 45 3339 6430

Fax

+98 45 3339 6430

Email

savalanm452@gmail.com

Web page address

<http://www.asproheal.com/>

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

Street address
Emam

City
Ardabil

Province
Ardabil

Postal code
۵۶۱۴۷۳۳۷۷۵

Phone
+98 45 3323 9033

Fax
+98 45 3323 2670

Email
mohammad.vakili@arums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Mohamad vakili

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Emam

City
Ardabil

Province
Ardabil

Postal code
۵۶۱۴۷۳۳۷۷۵

Phone
+98 45 3323 9033

Fax
+98 45 3323 2670

Email
mohammad.vakili@arums.ac.ir

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

Street address
Dastqeib

City
Ardabil

Province
Ardabil

Postal code
5613786179

Phone
+98 45 3339 6430

Fax
+98 45 3339 6430

Email
hamedaraz69@gmail.com

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

