

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the efficacy of Losartan ointment (an Angiotensin II Type I Receptor) in wound healing and preventing hypertrophic scars and keloids formation (useful in the injured military soldiers)

Protocol summary

Study aim

Evaluating the efficacy of losartan ointment (an Angiotensin II Type I Receptor) in wound healing and preventing hypertrophic scars and keloids formation

Design

a single-center double-blind, randomized, placebo-controlled, parallel-group, Randomised with block randomization method clinical trial, on 24 patients with acute surgical scar

Settings and conduct

The ointments will be placed in the same shape and colored bottles and a specific code will be attached to the bottles. Each time we will ask the patients to use each placebo and Losartan cream in a specific place twice a day for six months. Neither patient nor doctors or health care staff will know which cream (Placebo or drug) is administered in each site.

Participants/Inclusion and exclusion criteria

patient with more than 10 centimeters scar length and aged between 18 to 50 years old will included. Patients with irregular ointments consume or those who are pregnant, consume antihypertensive drugs or have a history of cancer, allergy, and bleeding or discharge at scar site will be excluded.

Intervention groups

A part of the scar treated with Losartan ointment. A part of the scare treated with Placebo ointment.

Main outcome variables

Vancouver Scar Scale assesses 4 variables, vascularity, height/thickness, pliability, and pigmentation will be use rate the scar change, and the Visual Analogue Scale will be used for itching.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201205049601N1**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **prospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

Behzad Khodai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7769 4460

Email address

khodaibehzad@alimnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of Losartan ointment (an Angiotensin II Type I Receptor) in wound healing and

preventing hypertrophic scars and keloids formation (useful in the injured military soldiers)

Public title

Evaluating the efficacy of Losartan ointment in wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's scar length should be more than 10 centimeter, or they should have several scars with total length of 10 centimeter. The patient's age should be between 18 to 50 years old.

Exclusion criteria:

The patients who did not regularly consume ointments will be excluded. The patients who are pregnant, consume antihypertensive drugs, or have history of cancer, allergy and bleeding or discharge at scar site will be excluded.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

The scars in different parts of the body for example left or right side of the abdomen or first 5 centemeter as a sample and second 5 centemeter of the scar as another sampel.

Randomization (investigator's opinion)

Randomized

Randomization description

In this double-blinded, parallel clinical trial, the block randomization method will be used using 4,6, and 8 block sizes. First, the patient's scar will be categorized into two groups (left and right). Then one side, for example, the right side, will be considered as a reference site. The intended treatment (Losartan ointment) will then be allocated using the block randomization method to the reference site. For example, if treatment (Losartan ointment) is allocated to the right side, the placebo will be automatically allocated to the left side. The following website will be used for generating a list of randomized interventions:

<https://www.sealedenvelope.com/simple-randomiser/v1/lists> The allocation will be concealed using the sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each Losartan and placebo ointment will be defined with a specific code. The ointments will be placed in the same

shape, and colored bottles, and the specific code will be attached to the bottles. Each time we will ask the patients to use each placebo and Losartan cream in a specific place twice a day for six months. Neither patient, caregivers, including nurses, nor doctors will know which cream (Placebo or drug) is administered in each site. The data will be collected using the Vancouver scar scale by doctors who had been blind to which drug is administered in each site. The corresponding researcher, the person who analysis the data and prepare the first draft of the article will not be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemad Zadeh St. ,Fatemi Ave. ,Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.AJAUMS.REC.1399.166

Health conditions studied

1

Description of health condition studied

wound healing and preventing hypertrophic scars and keloids formation

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Scare assessment, Vancouver Scar Scale (VSS) assesses 4 variables: vascularity, height/thickness, pliability, and pigmentation. The overall score is between 0 to 13.

Timepoint

Three and six months after ointment administration

Method of measurement

The evaluators are doctors who will use VSS or Vancouver scar scale to rate the scar change. Vancouver Scar Scale (VSS) assesses 4 variables: vascularity, height/thickness, pliability, and pigmentation. The overall score is between 0 to 13

Secondary outcomes

1

Description

Itching is an irritating sensation of the skin which will be measured by the Visual Analogue Scale.

Timepoint

Three and six months after ointment administration

Method of measurement

The evaluators are doctors and will be measured by the Visual Analogue Scale.

Intervention groups

1

Description

Intervention group: First a patient's scar will be categorized into two similar groups (Left and side). A Part of the scar selected randomly will be treated with Losartan ointment. The 5% Losartan ointment will be defined with a specific code. The ointment is going to be made by dissolving Losartan powder in a solvent including propanol and water and then mixed with eucerin to reach 100 mg weight. The patients will be asked to use 5% Losartan ointment tropically in the specified places twice a day every 12 hours for six continuous months.

Category

Treatment - Drugs

2

Description

Control group: First a patient's scar will be categorized into two similar groups (Left and side). A Part of the scar selected randomly will be treated with Placebo. The placebo consists of the solvent, including propranolol and water, and then mix it with eucerin to reach 100 mg weight and will not contain Losartan powder. The patients will be asked to use a 5% Losartan ointment tropically in the specified places twice a day every 12hours for six continuous months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Dermatology Hospital

Full name of responsible person

Dr Maryam Nasimi

Street address

Vahdat Eslami Square, Tehran, Iran. -Postal Code : 1199663911

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0174

Fax

Email

razihospital@sina.tums.ac.ir

Web page address

<http://razihos.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Farhad Motavali Khiavi

Street address

AJA University of Medical Sciences, Etemadi. Avenue, Fatemi Street , Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

nassireslami@razi.tums.ac.ir

Web page address

<https://www.ajaums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Behzad Khodai

Position

Medical Doctor (general practitioner)

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Unit 763, 2nd Floor, next to Hall Paradis, Vahidiyeh station, Damavand Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1644818411

Phone

+98 21 7769 4460

Email

khodaibehzad@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Behzad Khodai

Position

Medical Doctor (general practitioner)

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+98 21 7769 4460

Email

khodaibehzad@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

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Behzad Khodai

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Postal code

1644818411

Phone

+98 21 7769 4460

Fax**Email**

khodaibehzad@gmail.com

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

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

The study's findings will be published in a scientific paper in one of the scientific journals.

When the data will become available and for how long

After manuscript publication

To whom data/document is available

The researchers and others can access the report of trial results by the journal in which the article is published.

Under which criteria data/document could be used

No decision has been made yet.

From where data/document is obtainable

Please refer to the website of the journal in which the article will be published.

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

The researchers will access the clinical trial report and its results by downloading or buying the manuscript from the journal site.

Comments