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)

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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
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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Person responsible for updating data

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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
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