Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of topical ointment losartan versus placebo ointment on improvement of surgical scar: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of topical ointment losartan versus placebo ointment on improvement of surgical scar

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the stratified randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Sina Hospital in Hamadan city on 60 eligible patients with surgical scar. The patients will be randomly assigned to the intervention and control groups through the stratified randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 70 years Having a surgical scar Exclusion criteria: Pregnancy or breastfeeding The presence of a wound or infection at the treatment site Coagulation disorder or immune system disorder

Intervention groups
Intervention group: Applying losartan topical ointment on the surgical scar twice a day for 3 months Control group: Applying placebo topical ointment (eucerin) on the surgical scar twice a day for 3 months

Main outcome variables
Primary outcome: Improvement of surgical scar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N453**
Registration date: **2022-12-26, 1401/10/05**
Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**
Update count: **0**

Registration date
2022-12-26, 1401/10/05

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of topical ointment losartan versus placebo ointment on improvement of surgical scar: a double-blind randomized clinical trial

Public title
Effect of topical ointment losartan versus placebo ointment on improvement of surgical scar

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 70 years Age 18 to 70 years
Exclusion criteria:
Pregnancy or breastfeeding The presence of a wound or infection at the treatment site Coagulation disorder or immune system disorder

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of patients to intervention and control groups is done using stratified randomization method. For this purpose, first, patients are classified based on gender, age groups and type of lesion. Then randomization will be done through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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6517838695

Approval date
2022-10-29, 1401/08/07

Ethics committee reference number
IR.UMSHA.REC.1401.649

Health conditions studied

1

Description of health condition studied
Surgical scar

ICD-10 code
L90.5

ICD-10 code description
Scar conditions and fibrosis of skin

Primary outcomes

1

Description
Improvement of surgical scar

Timepoint
6 weeks and 3 months after treatment

Method of measurement
Using Vancouver scar scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Applying losartan topical ointment on the surgical scar twice a day for 3 months

Category
Treatment - Drugs

2

Description
Control group: Applying placebo topical ointment (eucerin) on the surgical scar twice a day for 3 months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital in Hamadan city

Full name of responsible person

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Sponsors / Funding sources

1

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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
Hamedan 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

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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
Undecided - It is not yet known if there will be 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