

# 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

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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

**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

**City**

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**Postal code**

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**

Dr Masoud Aftabi  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
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info.research@umsha.ac.ir  
**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

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr Masoud Aftabi

#### Position

Resident of Dermatology

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dermatology

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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**

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