

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of efficacy and safety of timolol gel versus placebo in wound healing of patients with split-thickness skin grafts

#### Protocol summary

##### Study aim

Efficacy and Safety of 0.25% Timolol Gel in Enhancing Split-Thickness Skin Grafts Healing Outcomes

##### Design

A randomized, blinded placebo-controlled clinical trial with a parallel group design of 60 patients. Patients will be assigned into two groups with a 1:1 ratio. Block randomization method will be used in this study.

##### Settings and conduct

Place: Zareh Sari Hospital. Vaseline gas will be placed in both groups. Participants will be rubbed daily with a fingertip per two square centimeters of wound area, timolol gel or gel-free base. The first dose will be given immediately after surgery and the intervention will continue for up to 14 days.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age over 18 years 2. Candidate for grafting Exclusion Criteria: 1. Pregnancy and lactation 2. Use of topical or systemic beta-blocker medications other than study medication 3. Sensitivity to timolol or other beta-blockers 4. Cases of which beta blocker is used with caution include diabetes, asthma and Chronic obstructive pulmonary disease 5. Use of systemic drugs that affect wound healing, such as retinoids and immunosuppressive drugs. 6. Severe coagulation disorders including coagulation factor deficiency and immuno-thrombocytopenic purpura

##### Intervention groups

Two groups including 0.25% timolol gel and base gel without active ingredient

##### Main outcome variables

The main consequence is the duration of epithelialization of wound bed in donor site.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090613002027N18**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

##### Registration date

2020-02-06, 1398/11/17

##### Registrant information

###### Name

Ebrahim Salehifar

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1311 6546

###### Email address

esalehifar@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

##### 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

Comparison of efficacy and safety of timolol gel versus placebo in wound healing of patients with split-thickness skin grafts

## Public title

The effect of timolol gel on wound healing in patients with skin transplantation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age  $\geq 18$  years of age Undergoing a procedure which results in the need of a STSG Willing to provide written informed consent

### Exclusion criteria:

Pregnant women and breastfeeding Use of systemic beta blockers drugs or topical except timolol Hypersensitivity to timolol or other beta blockers Severe, uncontrolled systemic comorbidities, such as diabetes, asthma, Chronic obstructive pulmonary disease Use of systemic drugs that can impede wound healing, such retinoids or immune-suppressive drugs Severe coagulation disorders including a lack of coagulation factors and immunologic thrombocytopenic purpura

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For allocation concealment, a 5 numbers digital code obtained from Excel software will be assigned for each patient. Participants will be randomly assigned to the study groups according to block randomization with 4 patients in each block. Random allocation software will be used for block randomization.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

For blinding purpose, instead of labels A or B, each participant will be assigned a unique fore-digit code obtained by the Excel program. Both timolol gel and placebo will be prepared in containers with equal appearance. Participants, physicians and assessor will be blinded regarding the grouping of participants.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar Square, Sari, Mazandaran Province

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

#### Approval date

2020-01-01, 1398/10/11

#### Ethics committee reference number

IR.MAZUMS.REC.1398.1257

## Health conditions studied

### 1

#### Description of health condition studied

Candidate Patients Receiving Skin Transplant

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Duration of wound epithelization in donor site of the transplant

#### Timepoint

The evaluation of wound on days 0 and 3 and 7 and 14 after surgery

#### Method of measurement

Clinical observation regarding the wound epithelization

## Secondary outcomes

### 1

#### Description

Pain severity

#### Timepoint

The evaluation times include days 0 (time of skin removal), 3, 7, 14 and 3 months after surgery

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Evaluation of the scar status

## Timepoint

Three months after surgery

## Method of measurement

Vancouver Scar Scale (VSS) and The Patient and Observer Scar Assessment Scale (POSAS)

## Intervention groups

### 1

#### Description

First Intervention: patients receiving 0.25% timolol gel  
The first dose will be applied immediately after the operation. The gel will be used twice daily for the first 48 hr and then daily until 14 days. The first four doses will be applied when the patient is in the hospital and then twelve single-dose units will be given for home use.

#### Category

Treatment - Drugs

### 2

#### Description

Second Intervention: patients receiving gel base without timolol  
The first dose will be applied immediately after the operation. The gel will be used twice daily for the first 48 hr and then daily until 14 days. The first four doses will be applied when the patient is in the hospital and then twelve single-dose units will be given for home use.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zareh Sari Hospital

##### Full name of responsible person

Ebrahim Salehifar

##### Street address

Sari Neka road

##### City

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##### Phone

+98 11 3328 3886

##### Email

esalehifar@mazums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

## Full name of responsible person

Majid Saeedi

## Street address

Moallem sq., Research and Technology Deputy of Mazandaran University of Medical Sciences

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+98 11 3448 4850

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+98 11 3354 3084

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majsaeedi@yahoo.com

## Grant name

## Grant code / Reference number

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

Yes

## Title of funding source

Sari 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

Mazandaran University of Medical Sciences

#### Full name of responsible person

Ebrahim Salehifar

#### Position

professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Clinical pharmacy

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Faculty of Pharmacy, Payambar Azam Complex, 18 Km Farah Abad Blvd, Khazar square, Sari, Mazandaran Province

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no plan for publishing the protocol of the study because it is accessible in IRCT.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data are shareable after publishing

**When the data will become available and for how long**

Start the access period 6 months after publishing the results

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Use in the practice and also future meta analysis

**From where data/document is obtainable**

Ebrahim Salehifar Email: Esalehifar52@gmail.com

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

Sending email to Dr Ebrahim Salehifar

**Comments**