

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 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

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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 ≥ 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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

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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

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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Latest degree

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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