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

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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
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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
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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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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