Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Topical Timolol on Wound Healing Following Fingertip Amputation: A Randomized Clinical Trial

Protocol summary

Study aim

To evaluate the effect of topical timolol 0.5% on accelerating wound healing and reducing infection in patients with fingertip amputations treated by secondary intention.

Design

Prospective, randomized, parallel-group, single-blinded clinical trial (outcome assessor). 1:1 allocation with permuted block design and complete concealment. Target sample size 88 (44 per group).

Settings and conduct

This prospective randomized clinical trial was conducted at Imtiaz and Chamran Hospitals from January 2023 to November 2024. Outcome assessors were blinded to treatment allocation.

Participants/Inclusion and exclusion criteria

Consecutive adults (≥18 years) with single, full-thickness distal fingertip amputation of the 2nd, 3rd, or 4th digit and soft-tissue loss ≤1.5×1.5 cm², presenting within 24 hours of injury; Exclusion: diabetes mellitus, autoimmune disease, peripheral vascular disease, significant cardiovascular disease, active smoking, pregnancy/lactation, β-blocker allergy/intolerance, concurrent systemic β-blocker use, or inability to provide informed consent.

Intervention groups

Timolol arm: Topical timolol maleate 0.5% ophthalmic solution, two drops applied once daily to the wound followed by sterile Vaseline gauze dressing. Control arm: Standard wound care with two drops of normal saline followed by identical Vaseline gauze dressing.

Main outcome variables

Time to complete wound epithelialisation (primary); Proportion of healed wounds at 2 weeks, 1 month and 4 months; Sensory recovery (two-point discrimination) at 4 months; Wound infection rate; Adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260702070046N1**
Registration date: **2026-07-08, 1405/04/17**
Registration timing: **prospective**

Last update: **2026-07-08, 1405/04/17**
Update count: **0**

Registration date

2026-07-08, 1405/04/17

Registrant information

Name

morteza solati kooshkqazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 4422 1853

Email address

mortezasolati1400@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2027-10-23, 1406/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Topical Timolol on Wound Healing Following Fingertip Amputation: A Randomized Clinical Trial

Public title
The effect of topical timolol on wound healing after fingertip amputation.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults 18 years and older A person visiting an emergency room or hand clinic with an amputated fingertip (second, third, or fourth finger) Full thickness excision with soft tissue loss up to 1.5 x 1.5 cm2 Visiting a medical center within 24 hours of the injury Ability to attend scheduled follow-up visits
Exclusion criteria:
Diabetes mellitus Autoimmune diseases Autoimmune diseases Significant cardiovascular disease Active smoking Pregnancy or lactation History of allergy or intolerance to beta-blockers Concurrent use of systemic beta-blocker medication Inability to give informed consent
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Enrolled patients were randomised 1:1 to the timolol or control arm using a computer generated randomisation sequence in permuted blocks of four and six
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was single-blind. Outcome assessors (clinicians performing wound inspection and two-point discrimination testing) were blinded to treatment allocation. However, patient blinding was not feasible due to the visible difference in the application method between topical timolol drops and normal saline drops.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz, Zand Street, Imam Hossein Square, Shiraz Medical School
City
shiraz
Province
Fars
Postal code
7134845794
Approval date
2025-10-07, 1404/07/15
Ethics committee reference number
IR.SUMS.MED.REC.1404.373

Health conditions studied

1

Description of health condition studied
Fingertip amputation (traumatic)
ICD-10 code
T92.6
ICD-10 code description
T92.6

Primary outcomes

1

Description
Time to complete wound epithelialisation
Timepoint
Assessed daily after the second week until complete wound closure, with confirmation at scheduled visits (2 weeks, 1 month, and 4 months post-injury). Time was recorded in days from the date of injury.
Method of measurement
Clinical confirmation by blinded assessor: intact epithelial coverage with no drainage and no need for further dressings.

Secondary outcomes

1

Description
Proportion of wounds completely healed
Timepoint
At 2 weeks, 1 month, and 4 months after injury
Method of measurement
Clinical assessment by blinded assessor for complete epithelial coverage with no drainage and no requirement for further dressings

2

Description
Sensory recovery measured by static two-point discrimination
Timepoint
At 4 months after injury
Method of measurement
Static two-point discrimination test using a standardized aesthesiometer; the smallest distance at which two points were perceived as distinct was recorded in millimeters, with the contralateral uninjured fingertip as reference

3

Description
Wound infection rate
Timepoint
Throughout the study period with particular attention at 2 weeks, 1 month, and 4 months
Method of measurement
Clinical criteria including traditional signs (abscess, cellulitis, purulent discharge) and additional indicators (delayed healing, malodour, friable granulation tissue, etc.)

Intervention groups

1

Description
Intervention group: Timolol maleate ophthalmic solution 0.5%, two drops (approximately 50 µl per drop) were applied to the wound surface once daily. After application of the drops, the wound was covered with sterile Vaseline gauze. Patients or caregivers received complete instructions on how to apply the drops and change the dressing.
Category
Treatment - Drugs

2

Description
Control group: Standard wound care included two drops of normal saline on the wound and then a Vaseline gauze dressing with a non-adhesive layer similar to the intervention group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imtiaz and Chamran Hospitals
Full name of responsible person
Dr. Alireza Zakaei
Street address
Imtiaz Hospital, Chamran Blvd., Shiraz, Fars Province, Iran
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Hamid Mohammadi
Street address
Shiraz, Zand Street, Shiraz University of Medical Sciences Central Building, 7th Floor, Vice President for Research and Technology
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Province
Fars
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7134814336
Phone
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Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Morteza Solati kooshkqazi
Position

Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Bandar Lengeh, Imam Hossein Blvd., 3rd floor, Islamic Azad University Building, Bandar Lengeh Branch

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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
Yes - There is 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Study protocol and clinical study report

When the data will become available and for how long
Available 6 months after publication of the main results

To whom data/document is available
Researchers from academic and scientific institutions

Under which criteria data/document could be used
For academic research purposes only, upon reasonable request and after signing a data use agreement

From where data/document is obtainable
Corresponding author via email mortezasolati1400@gmail.com

What processes are involved for a request to access data/document
Requests will be reviewed by the principal investigator. Approved requests will be fulfilled within 2-3 months after signing the data access agreement.

Comments