

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 $\leq 1.5 \times 1.5$ 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)

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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,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

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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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