

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of leech-therapy and wedge resection of finger nail on success rate of re-plantation in finger re-plantation patients

Protocol summary

Summary

This study is designed to compare effect of the two following methods on success rate of finger re-plantation: leech-therapy and wedge resection of finger nail. This work is a randomized clinical trial which will be done on 44 patients (22 patients by leech-therapy method and 22 patients by wedge resection of finger nail method). Inclusion criteria for the patients include requiring additional treatment for venous drainage during finger re-plantation and filling out the informed consent. Exclusion criteria include lack of filling out the informed consent, disagreement of the surgeon and surgeons' tendency to use leech-therapy and wedge resection of finger nail at the same time. Type of the treatment will be randomly selected based on a random number table. In leech-therapy method, leech is placed on the patient's finger with creating venous congestion (capillary refilling time of less than one sec). This process is repeated until the congestion is resolved and treatment intervals are adjusted according to the venous congestion. In another method, about one-third of the wedge nail is removed by a scalpel and is frequently stimulated by the gauze impregnated with heparin. Stimulation is repeated if venous congestion is induced. Completion criteria for the treatment are lack of venous congestion for 72 h without using any of the treatments or diagnosing necrotic finger by the surgeon. The surgeon will not be informed about the treatment process. Ultimately, success or failure of re-plantation is determined after observation and examination by the surgeon and the results of the two groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304288177N7**

Registration date: **2013-10-04, 1392/07/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-10-04, 1392/07/12

Registrant information

Name

Mohammad Javad Fatemi

Name of organization / entity

Burn Research Center of Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of leech-therapy and wedge resection of finger nail on success rate of re-plantation in finger re-plantation patients

Public title

The effect of leech-therapy on finger re-plantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients that require additional treatment for venous drainage during finger re-plantation. 2- Filling inform consent. Exclusion criteria: 1- Lack of informed consent. 2- Disagreement of surgeon. 3- Surgeons tend to use leech therapy and wedge resection of finger nail same time.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Postal code

1417653761

Approval date

2013-08-17, 1392/05/26

Ethics committee reference number

90-04-129-14929-91270

Health conditions studied**1****Description of health condition studied**

Finger amputation

ICD-10 code

S68.1

ICD-10 code description

Traumatic amputation of other single finger (complete)(partial)

Primary outcomes**1****Description**

Success of re-plantation surgery (survival and good venous drainage of replanted finger after two weeks)

Timepoint

Two weeks after surgery

Method of measurement

Observation, Examination

Secondary outcomes

empty

Intervention groups**1****Description**

Using leech-therapy for controlling venous congestion after finger re-plantation surgery Leech is placed on the patient's finger through creating venous congestion. Congestion will be relieved by blood suction of a leech. This process is repeated until congestion is resolved and treatment intervals are adjusted according to the venous congestion. Completion criteria of the treatment are lack of venous congestion for 72 h without using any of the treatments or diagnosing necrotic finger by the surgeon.

Category

Treatment - Other

2**Description**

Wedge resection of finger nail for controlling venous congestion after finger re-plantation surgery In this method, about one-third of the wedge nail is removed by a scalpel and is frequently stimulated by a gauze impregnated with heparin. Stimulation is repeated if venous congestion is induced. Completion criteria of the treatment are lack of venous congestion for 72 h without using any of the treatments or diagnosing necrotic finger by the surgeon.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatima Hospital

Full name of responsible person

Mohammad Javad Fatemi

Street address

Hazrat Fatima Hospital, Seyed Jamaledin Asadabadi Ave, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical

Full name of responsible person

Akbar Fotouhi

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Central Department of Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

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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

Vice chancellor for research of Tehran University of Medical

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hazrat Fatima Hospital

Full name of responsible person

Azam Skandari

Position

Bachelor of Nursing

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty