

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The comparison of treatment results of standard repair of traumatic injury of the distal half of the median nerve with applying laser therapy after repair

Protocol summary

Summary

Nerve injuries due to trauma to extremities are among the most important injuries that need special consideration. Nerve disruption or Neurotemesis is the most severe form of nerve damage in which the axones and their supportive structures lose their integrity and fall apart. In some studies, low power laser has been shown as a reinforcement factor in the procedure of nerve repair. Studies also showed that laser therapy after damage to inferior alveolar nerve following jaw surgeries, would reduce nerve impairment and accelerate remission. The goal of this study is the comparison of treatment results of standard repair of traumatic injury of the distal half of the median nerve with applying laser therapy after repair. Forty patients with sharp rupture at volar side of distal end of forearm, who have been admitted in the plastic surgery ward of Hazrate Fateme Hospital within seventy two hours after injury and have paraesthesia in 1st, 2nd and 3rd fingers, have been divided into two groups. First group undergo standard nerve repair and end to end anastomosis while the second group take ten sessions of low power laser therapy subsequently. First session of laser therapy would be after twenty four hours of surgery and the rest would be done each forty eight hours. EMG, NCV and physical exams' results will be recorded at the end of 3rd week, 3rd month and 6th month and at the end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204109431N1**
Registration date: **2012-05-31, 1391/03/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-31, 1391/03/11

Registrant information

Name

Siamak Farokh Forghani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 2974

Email address

siamakfarokh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of treatment results of standard repair of traumatic injury of the distal half of the median nerve with applying laser therapy after repair

Public title

Effect of laser on hand's nerve repair

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All the patients with sharp disruption on the distal end of forearm who have been admitted in the plastic surgery ward of Hazrate Fateme Hospital within seventy two hours after injury and have median nerve disruption. Exclusion criteria: Patients under 18 and over 60 years of age; concurrent Ulnar nerve injury; pregnant woman.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
16 Azar street

City
Tehran

Postal code

Approval date
2011-09-11, 1390/06/20

Ethics committee reference number
91.013.139470.7AA

Health conditions studied

1

Description of health condition studied
Forearm injury

ICD-10 code
S54.1

ICD-10 code description

Injury of median nerve at forearm level

Primary outcomes

1

Description
Fingers sensation

Timepoint
3 weeks, 3months and 6months after surgery

Method of measurement
Monofilament test, two points discremination test

2

Description
Fingers function

Timepoint
3 weeks, 3months and 6 months after surgery

Method of measurement
Thumb abdduction, opposition

Secondary outcomes

1

Description
tendon adhision

Timepoint
3rd week, 3rd month, 6th month

Method of measurement
fingers range of motions

2

Description
wound scar

Timepoint
3rd week, 3rd months, 6th month

Method of measurement
physical exam

Intervention groups

1

Description
10 sessions of low power laser therapy (DIOD LASER wavelenth 810 nm, power 50 mv, energy 4 j) with contact on anastomosis site. The first session during 24 hours after surgery and anothers with 48 hours interval.

Category
Treatment - Other

2

Description
Nothing

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fateme hospital

Full name of responsible person

Siamak Farokh Forghani

Street address

Fateme hospital, Yusef abad ave, 21 street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr Masood Younesian

Street address

Poorsina street, Keshavarz ave.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran university of medical sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Siamak Farokh Forghani

Position

resident of plastic surgery

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Web page address

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