Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of Low Level Laser therapy on repair of human digital flexor tendon repair

Protocol summary

Summary

The aim was investigation of low level laser on flexor tendon repair. In a randomized controlled trial, between April and September 2015, 39 patients with flexor tendon injury in the first 3 zones of their hand in 15Khordad hospital were enrolled for low level laser therapy randomized (just in odd days). Sample size was 96 fingers in two of low level laser and controlled groups. The end examination was double blind in clinical trial phase II. They got 8-10 session low level laser therapy with red and infrared lasers over flexor tendon repaired area. Red laser was continuous, 660 nm, and 2J/cm2. Infra red laser was pulse wave, 810 nm, 100 Hz, 5.85 J/cm2. Patients were visited in days 28-32 of surgery. Passive range of motion (PROM) was examined as double blind in 28 days. Underling diseases with impairment repair as diabetes or rheumatoid and extensor tendons simultaneously or under 10 years, were excluded. The only intervention was low level laser. Primary outcome variables was finger range of motion. Secondary outcome variables were pain and edema.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050233783N1**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Masoud Yavari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research project Shahid Beheshti University, Medical science.

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Low Level Laser therapy on repair of human digital flexor tendon repair

Public title

Early low level laser therapy improved passive range of motion and decreased pain in patients with flexor tendon injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusive criteria: All patients with hand injuries in 15khordad hospital at emergency department. Exclusion criteria: Underling diseases with impairment repair as diabetes or rheumatoid arthritis; multiple injuries to one flexor tendon; injuries to bone and extensor tendons

simultaneously; skin loss; non compliant patients or under 10 years; gross contaminations of wounds.

Age
From **15 years** old to **63 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **92**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Shahid Beheshti University of Medical Sciences

Street address
Near the Hospital Ayatollah Taleqani, Shahid Arabi Street, Yemen Street, Chamran Highway, Tehran, Iran

City
Tehran

Postal code
1985717443

Approval date
2015-05-17, 1394/02/27

Ethics committee reference number
SBMU.REC.1394.9

Health conditions studied

1

Description of health condition studied
Injury of flexor tendon of other finger at hand level

ICD-10 code
S66.1

ICD-10 code description
Injury of flexor muscle and tendon of other finger at wrist and hand level

Primary outcomes

1

Description
range of motion

Timepoint
end of survey

Method of measurement
ruler

Secondary outcomes

1

Description
pain

Timepoint
after of every low level laser session and end of survey

Method of measurement
questionnaire, 1 to 10 scale

2

Description
edema

Timepoint
end of survey

Method of measurement
centimeter

Intervention groups

1

Description
Intervention group: Irradiation of low level laser in the first to fourth weeks of injury in 8-10 sessions on wound region. Red laser in continuous mode, 660 nm, and 2J/cm2. Infra red laser in pulsed mode, wave 810 nm, 100 Hz, 5.85 J/cm2

Category
Treatment - Other

2

Description
Control group: no intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
15 khordad hospital

Full name of responsible person
Dr. Naghmeh Poorpezeshk

Street address
Sout Azodi Street, Karimkhan Avenue, Tehran, Iran.

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Near the Hospital Ayatollah Taleqani, Shahid Arabi Street, Yemen Street, Chamran Highway, Tehran, Iran
City
Tehran
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 Shahid Beheshti 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
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Full name of responsible person
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Person responsible for updating data

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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