

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 15Khardad 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

Country

Iran (Islamic Republic of)

Phone

+98 21889021559

Email address

m_yavari@sbmu.ac.ir

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 15khardad 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Naghmeh Poorpezeshk

Position

Fellowship Hand and Microsurgery

Other areas of specialty/work

Street address

Sout Azodi Street, Karimkhan Avneue, Tehran, Iran.

City

Tehran

Postal code

1598764514

Phone

+98 21 8890 1108

Fax

+98 21 8890 9193

Email

naghmeh_pr@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Dr. Masoud Yavari

Position

Fellowship Hand and Microsurgery

Other areas of specialty/work

Street address

Sout Azodi Street, Karimkhan Avneue, Tehran, Iran.

City

Tehran

Postal code

1598764514

Phone

+98 21 8890 1108

Fax

+98 21 8890 9193

Email

m_yavari@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Naghmeh Poorpezeshk

Position

Fellowship Hand and Microsurgery

Other areas of specialty/work

Street address

Sout Azodi Street, Karimkhan Avneue, Tehran, Iran.

City

Tehran

Postal code

1598764514

Phone

+98 21 8890 1108

Fax

+98 21 8890 9193

Email

naghmeh_pr@yahoo.com

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