

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The Comparison of clinical outcome Low Level Laser and Light Therapy on TKA patients: A randomized clinical trial

Protocol summary

Study aim

To evaluate the effects of LLLT and light therapy post knee replacement in order to enhance the quality of life

Design

Randomized, parallel groups trial with blinded outcome assessment. All the patients will allocated into 3 groups (Light, Laser and Control). In the present study, 45 patients were enrolled between 2018 Feb to 2019 Feb. Randomization was performed by the four-block technique.

Settings and conduct

The study will run in the Imam Khomeini Hospital. all the patients will allocated into 3 groups (Laser. Light and control). Patient and assessor who gathered the data were blinded about the type of treatment modality (Double-Blinded)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All patients who underwent TKA for primary knee osteoarthritis Exclusion Criteria: The patients with TKA due to secondary osteoarthritis such as rheumatoid arthritis and other rheumatologic condition, posttraumatic arthritis The patients who had cognitive dysfunction or mental retardation The patients with comorbidities such as diabetes or other neurological problems The revision TKA patients The patients who developed deep vein thrombosis or infections in postoperative period The patients who were unwilling to participate in the study

Intervention groups

light (Biopton light) in one intervention group and LLLT (R) laser) another group. First Group received Low-Level Laser during first 3 days after the operation in combination with exercise program with ice. (Laser) The second Group received (Biopton) light and the same exercise program quadriceps isometric with ice (Light) The third group just received an exercise program with ice as in all groups (Control).

Main outcome variables

The knee range of motion (ROM), Knee Society Score

(KSS), Functional KSS will measured preoperative and 3 months postoperative. Pain and swelling will measured preoperative and early postoperative.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160809029286N4**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **retrospective**

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Alireza Moharrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4401 7418

Email address

a-moharrami@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-02, 1396/11/13

Expected recruitment end date

2019-02-01, 1397/11/12

Actual recruitment start date

2018-02-02, 1396/11/13

Actual recruitment end date

2019-02-01, 1397/11/12

Trial completion date
2019-02-01, 1397/11/12

Scientific title
The Comparison of clinical outcome Low Level Laser and Light Therapy on TKA patients: A randomized clinical trial

Public title
The comparison of clinical outcome Laser and Light Method following Total Knee Arthroplasty

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients who underwent TKA for primary knee osteoarthritis at our institution The patients with informed consent to participate in the study
Exclusion criteria:
The patients with TKA due to secondary osteoarthritis such as rheumatoid arthritis and other rheumatologic condition, posttraumatic arthritis The patients who had difficulty in communication due to cognitive dysfunction or mental retardation The patients with comorbidities such as diabetes or other neurological problems Revision TKA patients The patients who developed deep vein thrombosis or infections in postoperative period The patients who were unwilling to participate in the study

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **15**
The sample size was calculated based on the study by Eid et al (2015) [28] that used LLLT for the treatment of hemarthrosis in hemophilic patients. For sample size calculation we considered the β value of 20% and α of 5%. We used the Range of knee flexion (ROM) 6 week after treatment (Group 1: 106 ± 5.7 Vs Group 2: 100.13 ± 4.99) as a reference value for sample size calculation. Therefore, the calculation resulted in 15 patients in each group and 45 patients in total
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the type of modalities we will use during rehabilitation after TKA, 45 patients will randomize into three groups including control, LLLT and light (15 patients per group). Randomization will performed by the four-block technique. Patient and assessor who will gather the data will blinded about the type of treatment

modality (Double-Blinded). We will use a randomization table and will divide all the patients into four blocks. The patients will allocate to three groups based on the treatment including Light, LLLT, and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization will performed by the four-block technique. Patient and assessor who will gather the data will blinded about the type of treatment modality (Double-Blinded). The patient and investigator will blinded about type of Intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences Ethic Committee

Street address
Imam Khomeini Hospital, End of Keshavarz blvd, Keshavarz Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2017-09-01, 1396/06/10

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4777

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee Society Score

Timepoint

Preoperative and 3 months post operative

Method of measurement

Based on the Knee Society Score form (0-100)

2

Description

Functional Knee Society Score

Timepoint

Preoperative and 3 months post operative

Method of measurement

Based on the Knee Society Score form (0-100)

3

Description

Pain Visual Analog Scale (VAS)

Timepoint

preoperative, first day, second day and third day
postoperative, 3 months post operative

Method of measurement

Based on the pain in Visual Analog Scale (VAS) (0-10 scores)

4

Description

Knee Range of Motion

Timepoint

preoperative, first day, second day and third day
postoperative, 3 months post operative

Method of measurement

Based on the measurement between full flexion and full extension by goniometer (0 to 140 degrees)

5

Description

Swelling

Timepoint

preoperative, first day, second day and third day
postoperative, 3 months post operative

Method of measurement

the measure around of proximal of leg base on mm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: light (Bioptron light) , The patients received (Bioptron) light and the same exercise program quadriceps isometric with ice which applied during first 3days after the operation.

Category

Rehabilitation

2

Description

Intervention group: LLLT (Low-Level Laser) or RJ laser, The patients received 804 nm GA AL AS LLLT (RJ laser) at power out of 500 mv and a degree of dosage 10J per session in 2 points (5J/Point) on posterior of the knee, which applied during first 3days after the operation. They receive same exercise and ice.

Category

Rehabilitation

3

Description

Control group: The Patients just received an exercise program with ice as in all groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Complex Hospital

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Street address

Imam Khomeini Hospital, End of Keshavarza Blvd, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Web page address

Http://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Joint Reconstruction Research Center

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 0000

Email

Imamhospital@tums.ac.ir

Web page address

Http://www.ikch.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

None

Proportion provided by this source

1

Public or private sector

Private

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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Moharrami

Position

Orthopaedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran , IRAN

City

Tehran

Province

Tehran

Postal code

1955743849

Phone

+98 21 6119 0000

Fax

Email

a-moharrami@student.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Seyed Mohammad Javad Mortazavi

Position

Hip and Knee surgeon

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6653 1354

Fax

Email

smjmort@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Moharrami

Position

Orthopaedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Orthopaedic Ward, Imam Khomeini Hospital, End of Keshavarz Blvd, Tehran , IRAN

City

Tehran

Province

Tehran

Postal code

1955743849

Phone

+98 21 6119 0000

Fax

Email

a-moharrami@student.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The article will published

When the data will become available and for how long

2021 January

To whom data/document is available

All faculty membership

Under which criteria data/document could be used

none

From where data/document is obtainable

Alireza Moharrami Email: a.moharramy@gmail.com

What processes are involved for a request to access data/document

please send Email

Comments