Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effects of High Intensity Laser Therapy(HILT) in comparison with Intra Articular Hyaluronic Acid(IAHA) injection on the pain and function of knee ostoarthrosis

Protocol summary

Study aim
Comparison of two methods of treatment in knee arthritis patients

Design
A randomized, single-blinded trial. The method of sampling is randomized patients with grade 1 or 2 knee osteoarthritis referring to affiliated and independent medical centers of Iran University of Medical Sciences.

Settings and conduct
place: Iran University Medical Science, Initially confirmation of knee arthritis by orthopedic surgeon and randomization of patients in three groups. For the injection group, 4 injections of IAHA are administered weekly and routine physiotherapy will be performed simultaneously with injection. For the HILT group, a weekly three times laser treatment with routine physiotherapy will be performed. For the placebo Laser Group, a weekly three times placebo Laser with routine physiotherapy will be performed. All groups are evaluated before, immediately after and one month after treatment. Blind: The evaluator is blind to what each patient is in.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals with knee arthritis with Grade 1 or 2 of kellgern-Lawrence classification. Not having rheumatic diseases; rupture of the ligament or meniscus; history of fracture; hyalgeal injection; or physiotherapy within recent 6 months. The absence of referral pain from the waist and pelvis VAS 4 or more WOMAC score 25 and above Exclusion criteria : lacking one of the Inclusion criteria Unwillingness to continue the research for any reason

Intervention groups
Group 1: patients who are treated with IAHA and routine physiotherapy. Group 2: patient who are treated with HILT and routine physiotherapy. group 3: patients who are receiving placebo laser and routine physiotherapy.

Main outcome variables
number of VAS scale, number of stiffness from WOMAC sub scale, number of pain from WOMAC sub scale, number of function from WOMAC sub scale, amount of edema, degree of knee ROM

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140810018754N9**
Registration date: **2018-11-03, 1397/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-03, 1397/08/12**
Update count: **0**

Registration date
2018-11-03, 1397/08/12

Registrant information

Name
Javad Sarrafzadeh

Name of organization / entity
Iran University of Medical Sciences, School of Rehabilitation Sciences

Country
Iran (Islamic Republic of)

Phone
00982122228051-00982122227124

Email address
sarrafzadeh.j@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-15, 1397/06/24

Expected recruitment end date
2019-06-20, 1398/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of High Intensity Laser Therapy(HILT) in comparison with Intra Articular Hyaluronic Acid(IAHA) injection on the pain and function of knee ostoarthrosis

Public title
The effects of high intensity laser therapy on knee ostoarthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Grade 1 or 2 knee osteoarthritis according to the Kellgren-Lawrence classification had a knee pain≥4 on the visual analog scale (VAS) do not injection corticostroid or hyaluronic acid in last six mount the gain 25 number in minimum condition from the WOMAC scale BMI < 30
Exclusion criteria:
existence RA, malignancy, knee surgery, fracture, menisqe or ligament tearing, genu varum or valgum above 20 degree, referal pain from hip or lumbar region doing physiotherapy in last six mount
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization Unit of randomization: personal Using the SPSS program
Blinding (investigator's opinion)
Single blinded
Blinding description
Examiner did not know that each simple present in witch group
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
5th floor, Iran University of Medical Sciences, Hemmat highway, between Sheikh Fazlollah Nuri and Chamran highways.
City
tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2018-08-25, 1397/06/03
Ethics committee reference number
IR.IUMS.REC.1397.197

Health conditions studied

1

Description of health condition studied
Knee ostoarthrosis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
intensity of pain
Timepoint
before starting the first treatment session, after the end of treatment session and one mount after the last of treatment session
Method of measurement
Visual analog scale (VAS)

2

Description
function and quality of life
Timepoint
before starting the first treatment session, after the end of treatment session and one mount after the last of treatment session
Method of measurement
persian WOMAC scal

3

Description
rang of motion of knee FLX and EXT

Timepoint
before starting the first treatment session, after the end of treatment session and one mount after the last of treatment session
Method of measurement
KROM device (degree)

4

Description
amount of knee odema
Timepoint
before starting the first treatment session, after the end of treatment session and one mount after the last of treatment session
Method of measurement
tape measure according in CM

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: This group constitutes patients with knee arthrosis, on the basis of Kellgren- Lawrence classification grade 1 or 2, whom received weekly (more accurately, for times a week) hyaluronic acid injection. The patients are to be undergone physiotherapy simultaneous with their getting the injections. the physiotherapy treatment comprises 20-minute IF current , US applied continuous for 5 minutes with 1 W/cm2 intensity, IR for 15 minutes, as well as the exercise training. The physiotherapy treatment must be performed weekly (triple a week) for 10 sessions.
Category
Treatment - Other

2

Description
Intervention group 2: This group constitutes patients with knee arthrosis, on the basis of Kellgren- Lawrence classification grade 1 or 2, receiving physiotherapy treatment as well as High Intensity Laser Therapy(HILT) . the laser's treatment protocol in the first three sessions is as follows: duty cycle:50%, frequency: 5000 Hz, Power density2.04 W, Energy density 10 J/cm2, treatment duration: 3 minute, the approximate treatment area : 100cm2 round the knee and the total apleid energy is 1000 J. However, the laser's treatment protocol in the next seven sessions is as follows:Power density 4.09 W, Energy density 50 J/cm2, treatment duration: 7 minute, the approximate treatment area : 100cm2 round the knee, the total apleid energy is 5000 J. and the laser's wavelength is 980 nm. The physiography treatment of this group comprises, as does the invention group 1, 20-minute IF current , US applied continuous for 5 minutes with 1 W/cm2 intensity, IR for 15 minutes, as well as the exercise training. The physiotherapy treatment must be performed weekly (triple a week) for 10 sessions.
Category
Treatment - Other

3

Description
Control group: This group constitutes patients with knee arthrosis, on the basis of Kellgren- Lawrence classification grade 1 or 2, receiving physiotherapy treatment as well as placebo High Intensity Laser Therapy (HILT), that is to say, the treatment is performed in a similar manner as to intervention group 2 ,though the laser fluency is lacking. As was the case for intervention group 1 and 2, the physiography treatment of this group comprises 20-minute IF current , US applied continuous for 5 minutes with 1 W/cm2 intensity, as well as the exercise training. The physiotherapy treatment must be performed weekly (triple a week) for 10 sessions.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahiaeian Medical Education Center
Full name of responsible person
Abolfazl Baqerifard
Street address
Shafa Yahiaeian Medical Education Center, Mojahedine Eslam St, Baharestan Sqr.
City
Tehran
Province
Tehran
Postal code
354-14665
Phone
+98 21 3354 2001
Email
baqerifard.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malakouti, Vice chancellor for research
Street address
5th Floor, Iran University of Medical Sciences, Hemmat highway
City
Tehran
Province

Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8670 2503

Email
research@iums.ac.ir

Web page address
http://vcr.iums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

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
Iran University of Medical Sciences

Full name of responsible person
Javad Sarrafzadeh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Physiotherapy department, School of Rehabilitation Sciences, Madadkaran street., Shahnazari street, Madar squ., Mirdamad street.

City
Tehran

Province
Tehran

Postal code
15459-13487

Phone
+98 21 2222 8051

Email
sarrafzadeh.j@iums.ac.ir

Web page address
http://rehab.iums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Javad Sarrafzadeh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Physiotherapy department, School of Rehabilitation Sciences, Madadkaran street., Shahnazari street, Madar squ., Mirdamad street.

City
Tehran

Province
Tehran

Postal code
15459-13487

Phone
+98 21 2222 8051

Email
sarrafzadeh.j@iums.ac.ir

Web page address
http://rehab.iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Javad Sarrafzadeh

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Physiotherapy department, School of Rehabilitation Sciences, Madadkaran street., Shahnazari street, Madar squ., Mirdamad street.

City
Tehran

Province
Tehran

Postal code
15459-13487

Phone
+98 21 2222 8051

Email
sarrafzadeh.j@iums.ac.ir

Web page address
http://rehab.iums.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data or results of the present study will be presented in an article or some articles that will be published after completing the study.

When the data will become available and for how long

After completing the present study and publishing the resulting article or articles.

To whom data/document is available

All researchers in the field of the present study.

Under which criteria data/document could be used

With the same goal as the present study and with mention of the present study as the reference. All intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

From where data/document is obtainable

The corresponding author of the article or articles derived from this study.

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

Written request from the author responsible for the present review after the publication of the resulting article or articles.

Comments