Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial comparison of the effect of low level and high level laser therapy (Ga-Al-Ar) and exercise therapy on the function and the pain of knee osteoarthritis

Protocol summary

Summary

The aim of this study is comparison the efficacy of gallium aluminum arsenide (Ga-Al-Ar) laser therapy (low level & high level) and exercise therapy on the function and pain of patients with grade 2 and 3 knee osteoarthritis. This study will be performed on 75 patients as a single center randomized of the phase 2-3 clinical trial and by simple randomized method (closed envelopes method and selecting color cards) in velayat hospital of Qazvin. Selected patients should have grade 2 and/or 3 osteoarthritis (OA). Kollgrn Lawreance system will be used to evaluate OA grading. The patients will be divided in to 3 groups; low level laser therapy (25 cases), high level laser therapy (25 cases) and exercise therapy (25 cases).The patients will be treated by laser therapy 3 times per week for 4 weeks (12 sessions). Outcome variable of knee pain intensity will be assessed before the treatment and during the first, second, third and forth weeks of treatment and also the first and forth weeks after the end of treatment by using laser and exercise therapies in each groups according to the visual analogue scales (VAS). Also, outcome variable of knee function will be assessed in a similar way according to the WOMAC questionnaire. The pain intensity will be assessed during the rest and activities.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011325994N1**
Registration date: **2016-03-10, 1394/12/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-10, 1394/12/20

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparison of the effect of low level and high level laser therapy (Ga-Al-Ar) and exercise therapy on the function and the pain of knee osteoarthritis

Public title

comparison the effect of laser and exercise on the function and the pain of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 50; patient with grade 2 and 3 osteoarthritis Exclusion criteria: Other knee joint disorder; Hip and/or foot osteoarthritis; serious systematic illness; Corticosteroid and Hyaloronic acid non-injection in knee joint during the past 6 months; knee effusion; knee surgery.

Age

From **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 the University of Medical Sciences

Street address

Shahid Bahonar Blvd.

City

Qazvin

Postal code

3419759811

Approval date

2012-06-19, 1391/03/30

Ethics committee reference number

5995/20/28

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17.9

ICD-10 code description

Gonarthrosis, unspecified

Primary outcomes

1

Description

knee pain intensity

Timepoint

The pain intensity before the treatment and the first, second, third and forth weeks and also the first and forth weeks after treatment by laser and exercise

Method of measurement

In all three groups based on the visual analogue scales (VAS)

2

Description

knee function

Timepoint

knee function before the treatment and the first, second, third and forth weeks and also the first and forth weeks after treatment by laser and exercise

Method of measurement

WOMAC questionnair

Secondary outcomes

empty

Intervention groups

1

Description

In first group, low level of laser(Ga-Al-Ar) 3 times per week for 4 weeks (12 sessions)

Category

Treatment - Other

2

Description

In second group, low level of laser(Ga-Al-Ar) 3 times per week for 4 weeks (12 sessions)

Category

Treatment - Other

3

Description

the third group will be taught isometric and isotonic strengthening and stretching exercises for quadriceps and hamstring muscles by training bulletin and face to face training.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Educational and Treatment Center
Full name of responsible person
Dr. Mahnaz Abbasi
Street address
Velayat Hospital, Taavon Sq., 22 Bahaman Blvd, Elahieh
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Qazvin University of Medical Sciences
Full name of responsible person
Dr. Taghi Naserpour Farivar
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Qazvin University Of Medical Sciences, Shahid Bahonar Blvd
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Qazvin
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 Qazvin 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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Person responsible for scientific inquiries

Contact
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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