Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of exercise therapy with and without intra-articular hyaluronic acid injection on the COP sway and its location in the base of support and physical function in patients with knee osteoarthritis

Protocol summary

Study aim

: Effect of exercise therapy with and without intra-articular hyaluronic acid injection on the COP sway and its location in the base of support and physical function in patients with knee osteoarthritis.

Design

randomized clinical trial with control group and single blind. 24 volunteer knee OA with HA injection and 12 patients without injection enrolled in this study. The patients with HA injection randomly divided in two exercise+HA injection and HA injection(N=12 in each group). Block randomization (permuted blocks of 3) was done using closed sealed envelope.

Settings and conduct

The patients were divided into 3 groups: Group exercise+ HAinjection received combination of 15 sessions of conventional exercise with three HA injections (1 injection weekly for 3 weeks), Group HA injection, received 3 intra-articular hyaluronic acid (1 injection weekly for 3 weeks) and control group performed the conventional exercise for 15 sessions. Outcomes measures were included some questionnaire (VAS,WOMAC, Lequesne, SF-36), COP sway in static balance,location of COP in the base of support,functional balance tests and lower limb muscle strength. All patients were evaluated before and 5 weeks after the beginning of the treatment.

Participants/Inclusion and exclusion criteria

: 36 volunteer patients with grade II or III of OA based on Kellgren-Lawrence (K/L) grading system), 45- 70 years(, and 15 age-matched healthy subjects without osteoarthritis, via simple non-probability method participated in this study exclude criteria: osteoporosis, flat foot, lower limb surgery, knee meniscus and ligament tears, diabetes, hyper tension

Intervention groups

Group intervention 1, intra-articular hyaluronic acid and conventional exercise (n=12), Group intervention 2, intra-articular hyaluronic acid and control group(n=12)

Main outcome variables

pain, quality of life, functional balance, static balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101017004952N10**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **retrospective**

Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date

2020-01-03, 1398/10/13

Registrant information

Name

Giti Torkaman

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4509

Email address

torkamg@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date
2017-01-19, 1395/10/30
Actual recruitment end date
2017-11-11, 1396/08/20
Trial completion date
2018-02-18, 1396/11/29

Scientific title
Effect of exercise therapy with and without intra-articular hyaluronic acid injection on the COP sway and its location in the base of support and physical function in patients with knee osteoarthritis

Public title
Effect of exercise therapy with and without intra-articular hyaluronic acid in knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
grade II or III of OA based on Kellgren-Lawrence the ages of 45 and 70 year Primary symptomatic knee osteoarthritis for at least 6 between No other treatments for 6 months prior to the study Pain for at least 3 months Muscle strength at least 3 using dynamometer
Exclusion criteria:
osteoporosis Participating muscle strengthening plan at least for 3 months ago Meniscal lesions Lower limb surgery Hard flat foot Knee valgus>15 and knee varus> 10 Corticosteroid injection in 6 months ago Suffering any other arthritis Serious systemic or nervous disease Visual disturbance Vestibular, neurologic, neuromuscular & chronic orthopedic disease Joint injury Severe muscle weakness
Age
From **45 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **36**
Actual sample size reached: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization (permuted blocks of 6) was done using closed sealed envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
assessor was blinded about the kind of intervention
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Tarbiat modares university
Street address
Jalal Al Ahmad Street
City
Tehran
Province
Tehran
Postal code
1411713116
Approval date
2016-03-02, 1394/12/12
Ethics committee reference number
IR.TMU.REC.1394.273

Health conditions studied

1

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

Primary outcomes

1

Description
balance,center of pressure sway
Timepoint
before and 5 weeks after the beginning of the treatment.
Method of measurement
Force plate

2

Description
CoP location in base of support
Timepoint
before and 5 weeks after the beginning of the treatment
Method of measurement
Force plate

Secondary outcomes

1

Description
Quality of life
Timepoint

before and 5 weeks after the beginning of the treatment.

Method of measurement

SF-36, WOMAC

2

Description

Functional activity

Timepoint

before and 5 weeks after the beginning of the treatment.

Method of measurement

6-min walk, timed up and go, star excursion, 8-walking test

Intervention groups

1

Description

Group intervention 1: Conventional exercise therapy and 3 intra-articular injection of Hyalgan in knee osteoarthritis patients (n=12)

Category

Rehabilitation

2

Description

Group intervention 2: three intra-articular injection of Hyalgan in knee osteoarthritis patients (n=12)

Category

Rehabilitation

3

Description

control group: Conventional exercise therapy in knee osteoarthritis patients (n=12)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat Modares University

Full name of responsible person

Giti Torkaman

Street address

Jala AleAhmad Ave., Nasr

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 4509

Email

torkamg@modares.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoub Fatholahi

Street address

Jalale Ale Ahmad

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 2009

Fax

+98 21 8800 6544

Email

res@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modares University

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

Tarbiat Modares university

Full name of responsible person

Giti Torkaman

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Jalal Al Ahmad St

City

Tehran

Province

Tehran

Postal code

1411713116

Phone
+98 21 8288 4509

Email
torkamg@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat modares university

Full name of responsible person
Giti Torkaman

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Jalal Al Ahmad St

City
Tehran

Province
Tehran

Postal code
1411713116

Phone
+98 21 8288 4509

Email
torkamg@modares.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat modares university

Full name of responsible person
Elham Rostami Mehr

Position
Graduated

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Jalal Al Ahmad St

City
Tehran

Province
Tehran

Postal code
1411713116

Phone
+98 21 8288 0000

Email
r.elham1370@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data will be shared after confirmation of chief researcher

When the data will become available and for how long
6 months after publication

To whom data/document is available
All researchers

Under which criteria data/document could be used
For scientific purposes

From where data/document is obtainable
Dr Giti Torkaman

What processes are involved for a request to access data/document
Confirmation of chief researcher

Comments