

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

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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

AgeFrom **45 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget 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

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Province

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Elham Rostami Mehr

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Graduated

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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