

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The effect of treadmill exercise with conventional physical therapy on the spatiotemporal parameters of the gait in subjects with bilateral moderate knee osteoarthritis

Protocol summary

Study aim

To determine the effect of treadmill exercise with conventional physiotherapy on the spatiotemporal parameters of the gait in subjects with Bilateral Moderate Knee OsteoArthritis

Design

Clinical trial of parallel intervention and control groups, sample size of 50 subjects, randomized, double blinded

Settings and conduct

Therapeutic study; at physical therapy section of Emam Mosa Kazem hospital and Musculoskeletal Research Center at Isfahan University of Medical Sciences. The participants, the assessor, the therapist and the analyzer will be blinded to the study groups. Data collection before & immediately after 10 sessions of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age 40-70 years 2.Bilateral moderate KOA 3.Stable baseline blood pressure Exclusion criteria: 1.Any uncontrolled metabolic, neurological (i.e. stroke, Parkinson, etc), cardiovascular problem that limits subjects ability to walk or cause gait abnormality. 2.Lower body fracture within 6 months. 3.Lower limb arthroplasty 4.Any acquired or congenital musculoskeletal dysfunction in lower limbs 5.Intra-articular steroid or hylan G-F 20 injection within the previous 6 months. 6.Inability to walk on a treadmill without an assistive device 7.History of any joint inflammatory disease. 8.Involvement in another treatment program or study protocol. 9.Involvement in any rehabilitation program within 6 months. 10.Patellofemoral dysfunction and acute low back pain

Intervention groups

All subjects will take part in conventional physical therapy program 3times a week, every other day for 10 sessions including: ultrasound, acupuncture TENS, moist hot pack, education (using an illustrated pamphlet) and setting exercise. The intervention group will have an

additional exercise.

Main outcome variables

Stride length; normalized stride length; average walking speed; cadence; stance time; stance percentage.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150131020888N10**

Registration date: **2018-11-23, 1397/09/02**

Registration timing: **retrospective**

Last update: **2018-11-23, 1397/09/02**

Update count: **0**

Registration date

2018-11-23, 1397/09/02

Registrant information

Name

Zahra Sadat Rezaeian

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2018-07-17, 1397/04/26

Actual recruitment start date

2017-08-01, 1396/05/10

Actual recruitment end date

2018-07-21, 1397/04/30

Trial completion date

2018-07-21, 1397/04/30

Scientific title

The effect of treadmill exercise with conventional physical therapy on the spatiotemporal parameters of the gait in subjects with bilateral moderate knee osteoarthritis

Public title

The effect of treadmill exercise in subjects with bilateral knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 40-70 years old Suffering from bilateral moderate knee osteoarthritis Stable baseline blood pressure

Exclusion criteria:

Any uncontrolled metabolic, neurological (i.e. stroke, Parkinson, etc) or any cardiovascular problem that limit subjects ability to walk or cause any gait abnormality Any altered sensation or nerve damage over the anterior knee(due to precaution in use of electrical currents like TENS) Lower body fracture within 6 months History of arthroplasty in either lower limbs Presence of any acquired or congenital musculoskeletal dysfunction in lower limbs Major loss of vision Intra-articular steroid or hylan G-F 20 injection within the previous 6 months Presence of a severe medical condition that precluded safe participation in an exercise or gait program Inability to walk on a treadmill without an assistive device History of any joint inflammatory disease Involvement in another treatment program or study protocol Involvement any rehabilitation program within 6 months Acute low back pain or patellofemoral disorders

AgeFrom **40 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **50**Actual sample size reached: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization base on random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The selected individuals will be informed about the study protocol in detail. They know that they will randomly be assigned into one of two groups that both will receive conventional physical therapy. They do not have the idea that by 50% they may be included in treadmill protocol. they only know that the exercise program is different between groups and there is 50% chance to be included in each group. they will be treated in the same place but not at the same time. Therefore, they do not have the opportunity to meet or observe the difference between groups. They do not know what kind of exercises are different between groups thus they will be blinded to groups' differences. The principal investigator (PI) will assign participant into treatment and control groups based on random number table. Employed physical therapist, who has no role in subjects evaluation, will manage both groups by a conventional physical therapy program. The same researcher who is blinded to study groups, will evaluate the subjects before and after 10 sessions of treatments in both groups. Data will be coded by PI and will be analysed by a analyzer who is blind to the study protocol.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University Of Medical Sciences, Isfahan, Iran

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81746-7346

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.MUI.REC.1396.3.309

Health conditions studied**1****Description of health condition studied**

Bilateral Moderate Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Spatio-temporal parameters of gait include stride length; normalized stride length; average walking speed; cadence; stance time; stance percentage.

Timepoint

Before and after 10 sessions of interventions in each groups

Method of measurement

Qualysis track manager

Secondary outcomes

1

Description

Pain

Timepoint

Before and after 10 sessions of interventions in each groups

Method of measurement

Visual analog scale(VAS); Intermittent and Constant Osteoarthritis Pain Score (ICOAP); Knee injury and Osteoarthritis Outcome Score (KOOS).

2

Description

Function

Timepoint

Before and after 10 sessions of interventions in each groups

Method of measurement

Knee injury and Osteoarthritis Outcome Score(KOOS); Six minute walk test and Get up and go test

3

Description

Gait biomechanics (kinetics and kinematics) parameters

Timepoint

Before and after 10 sessions of interventions in each groups

Method of measurement

Qualysis track system and visual 3D software

Intervention groups

1

Description

Intervention group: Ultrasound (1 MHz, 1.5-2 W, 5 minutes, continuous) that covers the antero-medial and antro-lateral aspects of the knee around the patella. Acupuncture TENS (low rate: 2-10 HZ, 200-300 microsecond, 20 minutes), four electrodes over the

superior and inferior medial and lateral poles of the patella. Hot moist pack for 20 minute. Quadriceps setting. Setting of the vastus medialis oblique (VMO). Education using an illustrated pamphlet. walking on the treadmill including one minutes walking with self-selected velocity [Warm-Up period], five minutes walking with gradual increase in velocity to reach threshold heart rate at the end of 5 minute. Threshold heart rate may be calculated as $HR_{Threshold} = 70\%HR_{Max}$ where $HR_{Max} = 220 - age$, seven minutes walking with controlling velocity to preserve participant's heart rate at threshold heart rate, one minute walking: self-selected velocity [Active Recovery] and five minutes rest at sitting position [Passive Recovery].

Category

Rehabilitation

2

Description

Control group: Ultrasound (1 MHz, 1.5-2 W, 5 minutes, continuous) 1-2 minute per 1 cm² that covers the antero-medial and antro-lateral aspects of the knee around the patella. Acupuncture TENS (low rate: 2-10 HZ, 200-300 microsecond, 20 minutes), four electrodes over the superior and inferior medial and lateral poles of the patella. Hot moist pack for 20 minute. Quadriceps setting. Setting of the vastus medialis oblique (VMO). Education using an illustrated pamphlet.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Mosa Kazem Hospital

Full name of responsible person

Zahra Sadat Rezaeian

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

396309

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

Yes

Title of funding source

Esfahan 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

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Position

PhD, Assistant Professor

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available