Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Muscoloskeletal 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

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Name of organization / entity
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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
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target 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 HRThreshold =70%HRMax where HRMax = 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
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Sponsors / Funding sources

1

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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

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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