Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of lower extremity Myofascial Release on knee stiffness,swelling and pain after Total Knee Arthroplasty

Protocol summary

Study aim
The effect of lower extremity Myofascial Release on knee stiffness,swelling and pain after Total Knee Arthroplasty

Design
Therapeutic groups consisting of two groups of ten people are selected based on simple randomization.

Settings and conduct
Treatment of patients in the physiotherapy Clinic of Rehabilitation of Tehran University for two groups of ten patients with total knee arthroplasty who receive a group of routine physiotherapy and another group, in addition to routine physiotherapy, receives myofascial release.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients over 60 years of age who have had total knee arthroplasty surgery.Patients have had contracure of flexion of 10 degrees. Exclusion criteria: Surgery other than Total Knee Arthroplasty, Revision TKA, Pain syndrome and acute infection, Rheumatoid arthritis, Motor neuron disease, Withdrawal from cooperation by the patient, Feeling uncomfortable and intolerant of pain by the patient, BMI over 40.

Intervention groups
Myofascial release is a manual technique performed as an intervention for a group of patients with knee arthroplasty. The other group receives only routine physiotherapy.

Main outcome variables
Active and passive range of motion by goniammeter, Pain by VAS scale, Swelling by meter, Quadriceps strength, SF-36, WOMAC.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210115050038N1**
Registration date: **2021-03-21, 1400/01/01**
Registration timing: **registered_while_recruiting**
Last update: **2021-03-21, 1400/01/01**
Update count: **0**

Registration date
2021-03-21, 1400/01/01

Registrant information

Name
Narjes Zoubin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3334 6777

Email address
nzoubin@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of lower extremity Myofascial Release on knee stiffness,swelling and pain after Total Knee Arthroplasty

Public title
Myofascial release in total knee arthroplasty

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
The patients over 60 years that have done surgery of

total knee arthroplasty. Patients have at least a contracture of flexion of ten degrees.

Exclusion criteria:

Surgeries other than total knee arthroplasty Revision TKA Pain syndrome and acute infection Deep venous thrombosis Fracture and scar Rheumatoid arthritis Motor neuron disease Withdrawal from cooperation by the patient Feeling uncomfortable and intolerant of pain by the patient BMI>40 kg/m2

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are randomly divided into two groups A and B ten. Random sequence through www.randomization.com so that each person with their eyes closed from inside a basket with numbers 1 to 20,pick a number to be in the group assigned to them by the site.Thus, patients are randomly divided into two groups of 10.

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

Tehran Medical University

Street address

School Of Rehabilitation Tehran Medical University, Piche-Shemiran, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

11489-65111

Approval date

2021-02-05, 1399/11/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1055

Health conditions studied

1

Description of health condition studied

Total Knee Arthroplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Active & Passive Range of motion, VAS, Quadriceps Strength, SF-36, WOMAC.

Timepoint

First&tenth session

Method of measurement

Goniammeter, meter, SF-36 & WOMAC form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group is a group that receives routine physiotherapy treatment and myofascial release as an intervener. Intervention is a type of manual massage performed by a physiotherapist and lasts about 5 minutes and does not require special equipment. The duration of treatment is ten sessions.The time of the physiotherapy session is about one hour. The evaluation of primary measures are done in the first session and tenth session.

Category

Treatment - Surgery

2

Description

Control group: The control group is the group that receives only routine physiotherapy.The duration of treatment is ten sessions.The time of the physiotherapy session is about one hour. The evaluation of primary measures are done in the first session and tenth session.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Of School Of Tehran Medical University

Full name of responsible person

Zoubin Narjes

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Rehabilitation of Tehran University, Piche-Shemiran, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
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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
Tehran Medical University
Proportion provided by this source
50
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
Tehran University of Medical Sciences
Full name of responsible person
Shadmehr Azadeh
Position
Professor
Latest degree
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Physiotherapy
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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The first outcome measures have to been assessed.

When the data will become available and for how long

From farvardin 1400 untile doing treatment of 20 cases.

To whom data/document is available

Consulting and Supervisor teachers

Under which criteria data/document could be used

Just for searching

From where data/document is obtainable

Rehabilitation Of School Of Tehran University, Piche-Shemiran, Tehran. dr. shadmehr

What processes are involved for a request to access data/document

Ten session of patient treatment are performed according to the surgeon`s instructions, routine physiotherapy.

Comments