

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of lumbopelvic manipulation on Electromyography parameters of gluteus medius and vastus medialis in patients with patellofemoral pain syndrome

Protocol summary

Study aim

The effect of lumbopelvic manipulation on electromyography parameters of gluteus medius and vastus medialis in patients with patellofemoral pain syndrome

Design

A concealed, randomized, double blinded, controlled Clinical trial design of 26 patients. permuted block method was used for randomization

Settings and conduct

This study is performed in the biomechanics laboratory of Babol University of Medical Sciences. After the patient's presence in laboratory, the examining physiotherapist performs an evaluation and electromyography(EMG). the lumbopelvic manipulation is performed by a physiotherapist who specializes in this area. The specialist physiotherapist performs lumbopelvic or sham-manipulation for the patient according to the randomization table. After the intervention and after resting the patient for 10 minutes, the examining physiotherapist enters the laboratory again, and while he is not aware of the type of intervention performed by the treating physiotherapist, the initial evaluation, tests and EMG are performed in the same way. Also, after one week, the examiner will follow up on the patients' condition by phone.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients under 40 years of age with anterior knee pain with no history of trauma and with patellofemoral pain syndrome diagnostic criteria
exclusion criteria: History of any pathological injury in the knee, lumbopelvic manipulation Contraindications, Taking painkillers or physiotherapy in the last 72 hours

Intervention groups

The subjects are divided into two groups and An intervention session is performed for them .for the first group The lumbopelvic manipulation is performed. And

for the second group, the sham manipulation is performed.

Main outcome variables

Electromyography parameters of gluteus medius and vastus medialis muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200818048446N1**

Registration date: **2021-09-11, 1400/06/20**

Registration timing: **retrospective**

Last update: **2021-09-11, 1400/06/20**

Update count: **0**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

khodabakhsh javanshir

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lumbopelvic manipulation on Electromyography parameters of gluteus medius and vastus medialis in patients with patellofemoral pain syndrome

Public title

The effect of lumbopelvic manipulation on patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients if they are aged less than 40 years unilateral anterior knee pain or a pain on palpation of patellar facets provoked by at least two of these activities: ascending/descending stairs, squatting, prolonged sitting, jumping, kneeling and Isometric quadriceps contraction positive sign in patellar apprehension test and/or eccentric step down test and/or vastus medialis coordination test a pain level of at least 3 points and maximum 8 points on the numerical pain rating scale(NPRS) during resisted knee extension knee disability level between 45 and 70 based on the Kujala patellofemoral questionnaire (KPQ) Have at least 3 of the 5 criteria to predict treatment success, including the following: The difference in the active range of motion of the internal rotation of the hip between the two limbs is more than 14 degrees- Dorsiflex active range of motion of the foot is more than 16 degrees- No stiffness after sitting for more than 20 minutes- Navicular drop- Squatting is most painful activity

Exclusion criteria:

a history of knee or spine surgery dislocation or fracture in pelvic meniscal lesion patellar subluxation/dislocation evidence of tendinopathy or ligamentous pathologies neurologic disorders patients who had previously received physiotherapy treatment used analgesic drugs within 72 h prior to the experiment osteoporosis with documented compression fracture severe lumbosacral nerve root compression signs pregnancy systemic disease or connective tissue disorders Lumbar disc rupture: extrusion, sequestration Serious spinal lesions include rheumatoid arthritis, tumors, vascular lesions of the spine, etc. spondylolisthesis and Specified lumbar instabilities

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

- Data analyser

Sample sizeTarget sample size: **26****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, participants are randomly divided into two groups by block randomization method with a fixed size of each block of 4. In this way, the list of random shifts of 4 letters A and B, which represent groups one and two, is generated with Random Allocation software and is the criterion for assigning individuals in groups. For example, if ABBA permutation is generated in the first block, it indicates that the first person is in group A, the second and third person in group B, and the fourth person in group A.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study, in the way that evaluation and treatment are done by two different people. And the evaluator is not aware of the type of grouping. Statistical analysis is also performed by a third person who does not know the grouping and treatment process. Patient blindness: Patients are told that manual therapy is to be performed on the lumbar, pelvic, and lower extremities, but they do not know the exact location and how. Patients are also not informed in which group they are. In the placebo (control) group, the patient is placed on a supine position and the therapist stands on the opposite side of the involved knee. The patient then locks the fingers behind her/his head and then passively moved to the side bend position by the therapist and rotated to the healthy position, and is in this position for five seconds. In the treatment group, the same steps are followed, with the difference that in the last stage, the thrust (high-speed movement of the therapist hand on the patient's ASIS) is applied. Patients are given time to participate in the project in such a way that they will not have any contact to share experiences.

Placebo

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

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

Ethics committee of Babol University of Medical Sciences

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Babol University of Medical Sciences, Ganj Afroz St

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Mazandaran
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۴۷۱۷۶-۴۷۷۴۵

Approval date
2020-08-16, 1399/05/26
Ethics committee reference number
IR.MUBABOL.REC.1399.248

Health conditions studied

1

Description of health condition studied
patellofemoral pain syndrome
ICD-10 code
M22.2
ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
onset of electromyography activity of vastus medialis muscle
Timepoint
Before and immediately after the intervention
Method of measurement
Surface electromyography device

2

Description
onset of electromyography activity of Gluteus medius muscle
Timepoint
Before and immediately after the intervention
Method of measurement
Surface electromyography device

3

Description
amplitude of electromyography activity of vastus medialis muscle
Timepoint
Before and immediately after the intervention
Method of measurement
Surface electromyography device

4

Description
amplitude of electromyography activity of Gluteus medius muscle
Timepoint
Before and immediately after the intervention
Method of measurement
Surface electromyography device

Secondary outcomes

1

Description
pain Intensity
Timepoint
Before, immediately after and one week after the intervention
Method of measurement
Numeric Pain Rating Scale

2

Description
Physical function
Timepoint
Before and immediately after the intervention
Method of measurement
step down test

3

Description
Knee joint functional level
Timepoint
Before, immediately and one week after the intervention
Method of measurement
Using kujala questionnaire

Intervention groups

1

Description
Intervention group: one session lumbopelvic manipulation: The patient was positioned supine while interlocking the fingers behind the head and the elbows are in contact with each other in the front. The patient's torso is in a neutral position and the therapist is on the patient's healthy side, then the patient was passively side-bent towards and rotated away from the painful knee. Stabilizer hand, Fix the patient's arms on the bed and The moving hand fix on the anterior superior iliac spine where the knee is involved. After getting loose, it applies a sudden thrust in the posterior-external-inferior direction. This technique is given in one session and then evaluated immediately and information is recorded.
Category
Rehabilitation

2

Description
Control group: one session sham manipulation: The patient is placed in the position of true lumbopelvic manipulation for 5 seconds, But the technique is not applied. After giving the position of the technique, the information is recorded.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahyanejad Hospital

Full name of responsible person

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Sponsors / Funding sources

1

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Tahere Zafarian

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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