

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the added effect of quadriceps dry needling on knee range of motion and pain in the primary phase of rehabilitation after anterior cruciate ligament reconstruction

Protocol summary

Study aim

Evaluation of the added effect of quadriceps dry needling on knee range of motion and pain in the primary phase of rehabilitation after anterior cruciate ligament reconstruction

Design

This study is a randomized clinical trial. Firstly, subjects get familiar with the methods, fill the consent form and characteristics form and then will be assigned into two groups by blocking randomization. Both groups receive routine physiotherapy treatments, but one group receive a real dry needle and the other group receive a sham dry needle for quadriceps muscle. Patients will be treated for four weeks (12 sessions) and dry needling will be received for four sessions (once each week). Knee range of motion and pain intensity will be assessed as outcome measures.

Settings and conduct

This study will be conducted in sport physiotherapy clinics of Shiraz and the suburbs. The assessor of knee pain and range of motion is unaware of subjects allocation into the groups of the study

Participants/Inclusion and exclusion criteria

inclusion criteria: Athletes from 18 to 45 years old undergoing ACL surgery using hamstring grafts for surgery, knee flexion of 90 degrees or less when referring to physiotherapy clinic (2 weeks after surgery), level 6 to 9 according to Tegner Questionnaire exclusion criteria: contraindications of the dry needle including fear of needle, diabetes, using anticoagulant drugs, and etc., any history of lower limb disorder or fracture prior to surgery that had limited knee range of motion, neuropathic pain or acute phase of local infection in lower extremity

Intervention groups

Intervention group 1: 12 sessions of routine knee physiotherapy and four sessions of quadriceps dry

needle Intervention group 2: 12 sessions of routine knee physiotherapy and four sessions of quadriceps sham dry needle

Main outcome variables

Knee range of motion pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181209041898N1**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **prospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

Registration date

2019-02-26, 1397/12/07

Registrant information

Name

Siroos Keramati fahliani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4260 0271

Email address

sirooskeramati@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-28, 1398/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the added effect of quadriceps dry needling on knee range of motion and pain in the primary phase of rehabilitation after anterior cruciate ligament reconstruction

Public title

The effect of the dry needle on pain and range of motion after anterior cruciate ligament reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 45 years Athletes with knee anterior cruciate ligament injury that is created during sportive activities undergoing ACL surgery and being referred to physiotherapy by a specialist, within two weeks after surgery using hamstring grafts for surgery knee flexion of 90 degrees or less when referring to physiotherapy clinic (2 weeks after surgery) level 6 to 9 according to Tegner Questionnaire

Exclusion criteria:

contraindications of the dry needle including fear of needle, diabetes, using anticoagulant drugs, and etc. any history of lower limb disorder or fracture prior to surgery that had limited knee range of motion Neuropathic pain or acute phase of local infection in lower extremity

AgeFrom **18 years** old to **45 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Permuted Block Randomization. Randomization was achieved with an online randomization application to provide random permuted blocks with a block size of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will be kept blinded to allocation to real or sham dry needling groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

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Province

Fars

Postal code

71348-14336

Approval date

2018-12-08, 1397/09/17

Ethics committee reference number

IR.SUMS.REHAB.RES.1397.004

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

Athletes who performed anterior cruciate ligament reconstruction surgery

ICD-10 code

S83.5

ICD-10 code description

Sprain of cruciate ligament of knee

Primary outcomes**1****Description**

Knee range of motion

Timepoint

at the beginning of the study and 7, 14, 21, and 28 days after the initiation of treatment

Method of measurement

Goniometry

Secondary outcomes**1****Description**

pain intensity

Timepoint

at the beginning of the study and 7, 14, 21, and 28 days after the initiation of treatment

Method of measurement

Numerical rating scale of pain

Intervention groups

1

Description

Intervention group 1: receiving 12 sessions (four weeks) of routine knee physiotherapy and one session of quadriceps dry needle in each week

Category

Rehabilitation

2

Description

Intervention group 2: receiving 12 sessions (four weeks) of routine knee physiotherapy and one session of quadriceps sham dry needle in each week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

sport physiotherapy clinics of Shiraz and the suburbs

Full name of responsible person

Siroos Keramati

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Shiraz University of Medical Sciences, Zand Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

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Web page address

<http://research.sums.ac.ir/fa/contact-information/index.html>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Rzaeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

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Position

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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

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Razeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work