

Clinical Trial Protocol

Iranian Registry of Clinical Trials

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EFFECTS OF QUADRICEPS KINETIC EXERCISES AT SPECIFIC KNEE ANGLE IN PATIENTS WITH POST-SURGICAL ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim

To examine the effects of specific quadriceps open and closed chain on knee function (pain, knee function, ROM and recurrence of ACL) after anterior cruciate ligament reconstruction surgery.

Design

Parallel group single blind randomized controlled trial

Settings and conduct

Physical Therapy Department, Northwest General Hospital & Research Center Peshawar, Pakistan and Rehman Medical Institute Peshawar, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age: 20-50 years, Both Gender Patients having Unilateral Anterior Cruciate Ligament reconstruction Healthy Contralateral leg ACL reconstruction surgery Ability to walk with or without an assistive device Exclusion Criteria: Any previous knee injury History of dislocation hip Concomitant injury Posterior Cruciate ligament Tear Any rheumatologic conditions Any trauma or meniscus injury History of Ligamentous instability at knee History of referred pain from the lumbar spine, hip, pelvis and sacroiliac regions Patients with history of remarkable knee joint inflammation and effusion, Patients with history of Hyperextension of knee joint Patients with history of polio paralysis Previous History of physiotherapy session for knee treatment

Intervention groups

Group-A: consisting of Controlled alternate quad and hamstring activity in open kinematic chain (OKC) plus Routine Physical Therapy Group-B: consisting of Controlled squats in closed kinematic chain (CKC) plus Routine Physical Therapy Group-C: (Combined Group) consisting of Controlled squats in closed kinematic chain (CKC) & controlled alternate quad and hamstring activity in open kinematic chain (OKC) plus Routine Physical Therapy All groups will get 60 Minute session, 3 days a

week alternatively for 12 weeks

Main outcome variables

Pain Knee Function Range of Motion Recurrence of ACL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200331046903N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Danish Ali Khan

Name of organization / entity

University of lahore

Country

Pakistan

Phone

+92 91 5813805

Email address

dani_ak_pk@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-15, 1399/01/27

Expected recruitment end date

2020-10-15, 1399/07/24

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
EFFECTS OF QUADRICEPS KINETIC EXERCISES AT SPECIFIC KNEE ANGLE IN PATIENTS WITH POST-SURGICAL ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: A RANDOMIZED CONTROLLED TRIAL

Public title
EFFECTS OF QUADRICEPS KINETIC EXERCISES AT SPECIFIC KNEE ANGLE IN PATIENTS WITH POST-SURGICAL ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION: A RANDOMIZED CONTROLLED TRIAL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 20-50 years Both male and female patients Patients having Unilateral Anterior Cruciate Ligament reconstruction Healthy Contralateral leg ACL reconstruction surgery Ability to walk with or without an assistive device

Exclusion criteria:

Any previous knee injury History of dislocation hip Concomitant injury Posterior Cruciate ligament Tear Any rheumatologic conditions (osteoarthritis, rheumatoid arthritis), Any trauma or meniscus injury History of Ligamentous instability at knee History of referred pain from the lumbar spine, hip, pelvis and sacroiliac regions Patients with history of remarkable knee joint inflammation and effusion, Patients with history of Hyperextension of knee joint Patients with history of polio paralysis Previous History of physiotherapy session for knee treatment

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The subject fulfilling the inclusion criteria will be enrolled by independent outcome assessor then lottery method will be used for randomization. Each member of the population will be number systematically and in consequent manner by writing each number on a separate piece of paper. These pieces of paper are mixed and put into a box and then numbers are drawn out of the box in a random manner. The subject's randomization method will reduce the chances of group bias allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single blinded in which outcome assessor will be kept blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of University Institute of Physical therapy University of Lahore

Street address

1- Km Raiwind Rd, Sultan Town, Lahore, Punjab

City

Lahore

Postal code

54792

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IRB-UOL-FAHS/695/2020

Health conditions studied

1

Description of health condition studied

Anterior Cruciate ligament Reconstruction

ICD-10 code

S83.519A

ICD-10 code description

Sprain of anterior cruciate ligament of unspecified knee, initial encounter

Primary outcomes

1

Description

Pain

Timepoint

before intervention and 6, 12 and 24 weeks after intervention

Method of measurement

Visual Analogue Scale

2

Description

Knee Function

Timepoint

before intervention and 6, 12 and 24 weeks after intervention

Method of measurement

Lysholm Knee Scoring scale

3

Description

Range of Motion

Timepoint

before intervention and 6, 12 and 24 weeks after intervention

Method of measurement

Goniometer

4

Description

Recurrence of Anterior Cruciate Ligament

Timepoint

before intervention and 6, 12 and 24 weeks after intervention

Method of measurement

Lachman Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1. Patients in this study group will get 60 Minute session, 3 days a week alternatively for 12 weeks consisting of Controlled alternate quad and hamstring activity in open kinematic chain (OKC) + Routine Physical Therapy, Modalities and Exercise for other body parts including contralateral lower limb, trunk, upper limbs, respiratory exercises.

Category

Treatment - Other

2

Description

Intervention group 2. Patients in this study group will get 60 Minute session, 3 days a week alternatively for 12 weeks consisting of Controlled squats in closed kinematic chain (CKC) + Routine Physical Therapy, Modalities and Exercise for other body parts including contralateral lower limb, trunk, upper limbs, respiratory exercises.

Category

Treatment - Other

3

Description

Intervention group 3. Patients in this study group will get 60 Minute session, 3 days a week alternatively for 12 weeks consisting of Controlled squats in closed kinematic

chain (CKC) & controlled alternate quad and hamstring activity in open kinematic chain (OKC) + Routine Physical Therapy, Modalities and Exercise for other body parts including contralateral lower limb, trunk, upper limbs, respiratory exercises.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Department Northwest General Hospital and Research Center , Peshawar, KPK, Pakistan

Full name of responsible person

Danish Ali Khan

Street address

Passport Office Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa

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Peshawar

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25100

Phone

+92 91 5838800

Email

dani_ak_pk@hotmail.com

Web page address

<https://www.nwgh.pk/contact-us>

2

Recruitment center

Name of recruitment center

Physical therapy Department Rehman Medical Institute Peshawar, Pakistan.

Full name of responsible person

Danish Ali Khan

Street address

Phase 5 hayatabad Peshawar Pakistan

City

Peshawar

Postal code

25100

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Lahore

Full name of responsible person

Prof Dr. Ashfaq Ahmad

Street address

1- Km Raiwind Rd, Sultan Town, Lahore, Punjab

City

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Postal code

54792

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+92 42 35963424

Email

ashfaaqpt@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of Lahore

Proportion provided by this source

100

Public or private sector

Private

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**

University of Lahore

Full name of responsible person

Danish Ali Khan

Position

PhD Scholar

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Prof Dr Ashfaq Ahmad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact**Name of organization / entity**

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Danish Ali Khan

Position

Phd Scholar

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

IPD collected for the primary outcome measure only
When the data will become available and for how long
after the publication of the study
To whom data/document is available
academic institutions and researcher
Under which criteria data/document could be used

on informed request from the investigators
From where data/document is obtainable
via email or telephonic contact with investigator
What processes are involved for a request to access data/document
on email request, data will be provided within week
Comments