

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effectiveness of early phase rehabilitation on outcomes of anterior cruciate ligament reconstruction in patients of tertiary care hospitals of Peshawar

Protocol summary

Study aim

The aim of the study is to assess the effects of early phase protocol in anterior cruciate ligament reconstruction patients in addition to conventional physical therapy protocol.

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

Study will be conducted at Hayatabad medical complex, Khyber teaching hospital and Lady reading hospital, Peshawar.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient underwent through ACL reconstruction surgery using hamstring and peroneus longus graft, Both males and females, aged 18 to 40 years. Exclusion criteria: Patients with medial collateral ligament injuries, meniscal injuries and infections, Patients with known neurological diseases, Patients with known cognitive impairment.

Intervention groups

Group A will receive routine/conventional therapy while Group B will receive conventional plus Fowler Kennedy's protocol. All the participants will be assessed for base line measurements i.e. range of motion to the opposite knee, joint swelling, neuromuscular control and muscle strength. Both groups will be followed for two weeks.

Main outcome variables

1. Lower Extremity Functional Score (LEFS) 2. Numeric Pain Rating Scale (NPRS) 3. Goniometer for Range of motion 4. Cincinnati knee rating system (CKRS) 5. Tegner Lysholam knee activity scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056821N1**

Registration date: **2023-01-07, 1401/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-07, 1401/10/17**

Update count: **0**

Registration date

2023-01-07, 1401/10/17

Registrant information

Name

Mashal Gul

Name of organization / entity

Khyber Medical University

Country

Pakistan

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-20, 1401/09/29

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of early phase rehabilitation on

outcomes of anterior cruciate ligament reconstruction in patients of tertiary care hospitals of Peshawar

Public title

Rehabilitation for anterior cruciate ligament reconstruction patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient underwent through ACL reconstruction surgery using hamstring and peroneus longus graft Both males and females, aged 18 to 40 years

Exclusion criteria:

Patients with medial collateral ligament injuries, meniscal injuries & infections. Patients with known neurological diseases Patients with known cognitive impairment

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects will be randomly assigned to one of two groups using sealed envelope method: one (the experimental group) receiving the intervention, and the other (the comparison group or control) receiving an alternative (conventional) treatment

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to nature of study, it will not be feasible to blind therapist and subjects. However, assessor, who will assess pre and post measurements, will be blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AS&RB (Advanced Studies & Research Board) and ethical committee of Khyber Medical University

Street address

Phase 5 Hayatabad

City

Peshawar

Postal code

25000

Approval date

2021-10-19, 1400/07/27

Ethics committee reference number

KMU/AS&RB/MSPT/2021/27

Health conditions studied

1

Description of health condition studied

ACL reconstruction rehabilitation

ICD-10 code

S83.50

ICD-10 code description

Sprain of unspecified cruciate ligament of knee

Primary outcomes

1

Description

Lower Extremity Function

Timepoint

Baseline Assessment and Assessment after 2 weeks of intervention

Method of measurement

Lower Extremity Function Score

2

Description

Pain

Timepoint

Baseline Assessment and Assessment after 2 weeks of intervention

Method of measurement

Numeric Pain rating Scale

3

Description

Range of motion

Timepoint

Baseline Assessment and Assessment after 2 weeks of intervention

Method of measurement

Goniometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Heel slides (slider board), Supine

with legs up wall heels slides with gravity assisted, Bike pendulums: high seat circles forward and backward full circles lower seat Sitting passive leg extension with roll under heel OR prone leg hangs off end of bed Seated calf stretch with towel, knee bent (soleus), knee straight (gastrocnemius), Seated hamstring stretch (back straight), Quadriceps and hamstring co-contraction, Quadriceps isometrics in standing, sitting, lying +/- muscle stimulation or biofeedback, Sit to stand progress by gradually decreasing height of seat, Static lunge forward/side, Mini wall squat (30°), Side lying abduction and adduction, Gluteal squeezes supine or standing, Prone hip extension, Standing hip flexion and extension, abduction/adduction, Ankle pumping +/- with leg elevation, Standing calf raises with and without support, Single leg stance 30 to 60 seconds, Wobble boards with support (table, bars, poles) through full ROM: side to side, forward and backward, Weight shifting: side to side and forward and backward, Progress from 2 crutches to 1, always maintaining normal walking pattern, Ice 15-25 minutes, Interferential current therapy (pain relief), Muscle Stimulation.

Category

Rehabilitation

2

Description

Control group: Icing 10-15 minutes, Gluteal squeezes supine or standing, Prone hip extension, standing hip flexion and extension, abduction and adduction, Ankle pumping +/- with leg elevation, standing calf raises with/without support, Single leg stance 30-60 seconds.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hayatabad Medical Complex, Peshawar

Full name of responsible person

Khalid Khan

Street address

Phase-4 Phase 4 Hayatabad, Peshawar, Khyber Pakhtunkhwa

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khyber Medical University

Full name of responsible person

Mujeeb Ur Rahman

Street address

F1 Phase-6 Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa

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25100

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+92 333 2251226

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mujeeb.rahman@kmu.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Khyber 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

NCS University System

Full name of responsible person

Mashal Gul

Position

Senior Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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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

The institute as well as my patients I am working with is not allowing me to share data

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