Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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 weeeks 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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Peshawar

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25000

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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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Peshawar

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25100

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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
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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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