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Robotic exoskeleton versus continuous passive motion for rehabilitation after total knee arthroplasty

Submission date
17/06/2026

Recruitment status
No longer recruiting

Registration date
22/06/2026

Overall study status
Completed

Last Edited
22/06/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study compares two rehabilitation methods for patients who have undergone total knee replacement surgery.

Who can participate?
Patients aged between 48 and 75 years with a confirmed diagnosis of end-stage knee osteoarthritis treated by unilateral total knee arthroplasty.

What does the study involve?
One group received therapy using a robotic exoskeleton device that assists walking and knee movement. The other group received Continuous Passive Motion (CPM) therapy, where a machine gently moves the knee. Both groups had 45-minute sessions, 5 days a week, for 4 weeks. The study measured pain, walking ability, knee movement, and functional status before and after treatment.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
School of Science and Engineering, Sharif University of Technology, Iraq.

When is the study starting and how long is it expected to run for?
September 2024 to April 2026.

Who is funding the study?
School of Science and Engineering, Sharif University of Technology, Iraq.

Who is the main contact?
Dr Raed Alalwani, raed.abdalamer@atu.edu.iq

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title
Effectiveness of robotic exoskeleton versus continuous passive motion on rehabilitation outcomes following total knee arthroplasty: a comparative clinical study

Study objectives
To compare the effectiveness of robotic exoskeleton therapy versus Continuous Passive Motion (CPM) on pain, functional mobility, range of motion, and walking ability in patients following total knee arthroplasty.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/01/2024, Al Furat Alawsat Technical University (Almussaib, babelon, 79417-76655, Iraq; +964 7702793694; isam_jettar@yahoo.com), ref: SUT-EC-2024-001

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment

Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Knee osteoarthritis; total knee arthroplasty (TKA); post-surgical rehabilitation

Interventions
Group 1 (Exoskeleton): Lower-limb robotic exoskeleton therapy, 45 minutes per session, once daily, 5 days per week, for 4 weeks (20 sessions total). Progressive gravity-compensated assistance at the knee joint.

Group 2 (CPM): Continuous Passive Motion therapy, 45 minutes per session, once daily, 5 days per week, for 4 weeks (20 sessions total). Initial ROM 0-45 degrees, incrementally increased by 5-10 degrees per session.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Robotic lower-limb exoskeleton device, Continuous Passive Motion (CPM) machine

Primary outcome(s)
1. Functional walking capacity measured using 6-Minute Walk Test (6MWT) - distance in metres at baseline and 4 weeks post-intervention

Key secondary outcome(s)
1. Pain intensity measured using Visual Analogue Scale (VAS) 0-100 at baseline and 4 weeks post-intervention

Completion date
17/04/2026

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of end-stage knee osteoarthritis treated by unilateral total knee arthroplasty
2. Age between 48 and 75 years
3. Ability to comprehend and follow verbal instructions
4. Absence of concurrent severe systemic disease

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
48 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Revision TKA or prior ipsilateral knee surgery within 6 months
2. Severe cognitive impairment affecting participation
3. Neurological conditions affecting lower limb function
4. Contraindications to physical therapy or weight-bearing activities

Date of first enrolment
04/09/2024

Date of final enrolment
10/08/2025

Locations

Countries of recruitment
Iraq

Sponsor information

Organisation
Sharif University of Technology

ROR
https://ror.org/024c2fq17

Funder(s)

Funder type

Funder Name
Sharif University of Technology

Alternative Name(s)
, SUT

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Iran

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			22/06/2026	No	No