

Evaluation of the Imperial College Prosthetic Suspension Systems in providing increased limb control and comfort

Submission date 06/01/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 08/01/2026	Overall study status Ongoing	☐ Protocol
Last Edited 18/05/2026	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)

Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

In adult lower-limb prosthesis users in Cambodia, are the Imperial College Prosthetic Suspension Systems, compared with existing prostheses and basic cushion liners, effective in providing increased limb control and comfort?

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/11/2025, National Ethic Committee for Health Research (NECHR) (#80, Samdach Penn Nouth Blvd, Sangkat Boeungkok 2, Khan Tuol Kork, Phnom Penh, 120408, Cambodia; +855 012 528 789; nouthsarida@gmail.com), ref: 714

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Crossover

Purpose

Device feasibility, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied

Unilateral transtibial or transfemoral amputation

Interventions

Two novel prosthetic suspension systems (pin lock and lanyard) for integration with ICRC polypropylene prostheses have been developed by colleagues at Imperial College London. These will be provided to participants (50% pin lock, 50% lanyard. Assigned randomly) and compared

with both their original prosthesis (PE-lite liner), as well as a control prosthesis that uses a cushion liner. Each device will be provided for a minimum of 8 weeks, with measurements taken at 0, 2, 4, and 8 weeks. Half of the participants will start with the control prosthesis, and the other with the novel prosthesis. After 8 weeks, they will swap to their other prosthesis. The research protocol will be conducted in several phases, and consists of data collection from the participant in the following ways:

1. Questionnaires (Prosthetic Limb Users Survey of Mobility - PLUS-M, Modified Satisfaction with Prosthesis – SAT-PRO)
2. Quantitative measurements of mobility and pistoning captured by prosthetists.

Intervention Type

Device

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

Imperial College Pin-Lock Suspension System, Imperial College Lanyard Suspension System, Cushion Liners, PE-lite liners

Primary outcome(s)

1. Effect on amputee daily life measured using Questionnaires (PLUS-M and SATPRO) and measurements (Pistoning and 2MWT) at 0, 2, 4, and 8 weeks

Key secondary outcome(s)

Completion date

04/12/2026

Eligibility

Key inclusion criteria

1. $18 \leq \text{age} \leq 60$ years old
2. Weight ≤ 100 kg
3. Unilateral transfemoral or transtibial amputee
4. Experienced prosthesis user (> 18 months)
5. Has been an amputee for > 24 months
6. Healthy (no other disability or health issues other than lower limb amputation)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Total final enrolment

32

Key exclusion criteria

1. Age < 18 years old, or 60 years old < age
2. 100 kg < Weight
3. Bilateral amputation
4. Any other recognised disability other than lower limb amputation
5. Pregnant
6. Unable to provide consent for the procedures detailed in the protocol
7. Has undergone lower-limb surgery in the last 6 months

Date of first enrolment

18/06/2025

Date of final enrolment

31/12/2025

Locations**Countries of recruitment**

Cambodia

Study participating centre

Department of Prosthetics and Orthotics in the Faculty of Prosthetic and Orthotic Engineering at the National Institute of Social Affairs (DPO)

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Cambodia

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Sponsor information**Organisation**

National Institute for Health Research

ROR

<https://ror.org/0187kwz08>

Funder(s)

Funder type

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 1.2		07/01/2026	No	No
Other files			07/01/2026	No	No
Other files			07/01/2026	No	No
Other files			07/01/2026	No	No
Other files	version 1.2		18/05/2026	No	No
Other files	version 1.1		18/05/2026	No	No
Participant information sheet			07/01/2026	No	Yes
Participant information sheet			18/05/2026	No	Yes