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

Submission date	Recruitment status	[ ] Prospectively registered
06/01/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/01/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/01/2026	Injury, Occupational Diseases, Poisoning	[X] Record updated in last year

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

Contact information

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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
31/05/2026

Eligibility

Key inclusion criteria
1. 18 ≤ age ≤ 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)
-
-
Cambodia
-

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			07/01/2026	No	No
Other files			07/01/2026	No	No
Other files	version 1.2		07/01/2026	No	No
Other files			07/01/2026	No	No
Participant information sheet			07/01/2026	No	Yes