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STEPFORWARD: Patient acceptability of a novel prosthetic device

Submission date 16/04/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/04/2018	**Overall study status** Completed	
Last Edited 24/04/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Annually, 6,000 people in the UK are referred for fitting of an artificial lower leg (known as a prosthesis) after the surgical removal of their limb (lower-limb amputation). These are mostly patients over 50 years and usually have diabetes and/or blood vessel (vascular) problems. Older patients are often prescribed standard foot-ankle prostheses which are rigid at the “ankle”, unlike those often given to younger people which can adjust to slopes and stairs. It is unknown which is the best prosthesis for older patients. The aim of this study is to see whether it is possible to do a large study comparing the standard foot-ankle prosthesis to a new version, by first carrying out a smaller study.

Who can participate?
Patients aged over 50 with a below-knee amputation because of vascular problems and who find walking difficult

What does the study involve?
Participants are randomly allocated into one of two groups to wear either their existing prosthesis or a new prosthesis for 12 weeks. One-to-one interviews are held to ask patients how they felt about participating in the study. The researchers measure how far patients can walk, how long they wear their prosthesis daily, and ask them to score their pain, health and well-being. This is done with questionnaires, simple exercise tests and a wearable device which measures activity.

What are the possible benefits and risks of participating?
Participants may not directly benefit from this study but taking part could help build up the evidence about how beneficial the new prosthesis is compared to standard prostheses. No risks are expected, but participants in the new prosthesis group may find that it can take them some time to adjust to the new prosthetic, therefore they could slip or stumble as they adjust to it.

Where is the study run from?
1. Hull & East Yorkshire NHS Trust (UK)
2. Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2018 to March 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Natasha Mitchell

Contact information

Type(s)
Scientific

Contact name
Dr Natasha Mitchell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37815

Study information

Scientific Title
STEPFORWARD: Patient acceptability of a novel prosthetic device: a randomised feasibility study in older patients with vascular-related amputations and multimorbidities

Acronym
STEPFORWARD

Study objectives

To assess the feasibility of conducting a future, full scale randomised controlled trial into the effectiveness and cost-effectiveness of a novel prosthesis for older patients with vascular-related amputations and other health issues compared to a standard prosthesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & the Humber - Leeds West, 09/03/2018, ref: 18/YH/0089

Study design
Randomised; Both; Design type: Treatment, Process of Care, Device, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Disorder of arteries and arterioles, unspecified

Interventions
Multi-centre, randomised controlled, open feasibility study, using a 1:1 randomisation ratio, patients will be block randomised, stratified by prosthetics centre.

The study will look at the randomisation process, recruitment and whether patients found the study processes acceptable. Over two years, the trialists want to recruit 90 older people with a below-knee amputation because of vascular problems and who find walking difficult. They will invite patients from three prosthetics centres across England to participate and they will be placed randomly into one of two groups by a computer: wearing 1) their existing prosthesis or 2) a new prosthesis for 12 weeks. There will be one-to-one interviews to ask how patients felt about participating in the study. The trialists will measure how far patients can walk, how long they wear their prosthesis daily, and ask them to score their pain, health and well-being. They will do this with questionnaires, simple exercise tests and a wearable device which measures activity.

Intervention Type
Other

Primary outcome measure
The feasibility of conducting a future, full scale RCT into the effectiveness and cost-effectiveness of a novel prosthesis for older patients with vascular-related amputations and other health issues compared to a standard rigid prosthesis. This will be assessed based on whether:
1. Study consent/retention rates and proposed sample sizes indicate recruitment for the full-scale RCT is plausible within a 24-month period
2. Outcome measures and fidelity evaluation data are successfully collected
3. There are no significant barriers to delivery of the trial identified by participants or recruiting centres

Secondary outcome measures
1. Patient recruitment rate
2. Barriers to recruitment, how these might be overcome from the perspective of patients, and the most important outcomes to them
3. The acceptability of the study procedures to both participants and recruiting centres
4. Patient use of NHS resources over the study period related to the research
5. Identify a primary outcome measure(s) for a future main trial (if feasibility is established)
6. The completeness of follow-up to establish how feasible it is to collect patient-reported outcome measures including data related to patient function, health status, adverse events and use of the NHS
7. Day-to-day use of the prosthesis in both groups and measure normal physical activity through the use of wearable technologies (activity monitors)

Overall study start date
01/04/2018

Completion date
31/03/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/05/2018:
1. Aged over 50 years
2. Has a unilateral amputation
3. Has a below-knee amputation only
4. Has an amputation due to vascular reasons (diabetes, peripheral vascular disease), neurological disorders (i.e. diabetic neuropathy) or life-limiting illness (i.e. tumour, cancer)
5. Is categorised as 'limited mobility' (K2 classification or SIGAM mobility grade C or D)
6. Is currently using a standard prosthetic foot-ankle (e.g. SACH, uniaxial, multiflex or other K1 /K2 feet) that does not adjust to sloped surfaces and is not self-aligning
7. Has been using a prosthesis for at least 12 months, with the same socket for a minimum of 3 months
8. Has had a stable residual limb for at least 3 months (i.e. stable in volume and without cuts or wounds; daily management of volume with socks and liners is acceptable)
9. Is willing to trial a new prosthesis for a 12-week period (if allocated to intervention arm)
10. Is able to self-complete the English language outcome measure tools (or complete with assistance)
11. Is able to follow the detailed verbal instructions required for the functional/clinical tests
12. Is able to provide written informed consent

Previous inclusion criteria:
1. Aged over 50 years
2. Has a unilateral amputation
3. Has a below knee amputation only
4. Has an amputation due to vascular reasons (diabetes, peripheral vascular disease), neurological disorders (i.e., diabetic neuropathy) or life-limiting illness (i.e. tumour, cancer)
5. Is categorised as 'limited mobility' (K2 classification or SIGAM mobility grade C or D)
6. Is currently using a standard prosthetic foot-ankle (e.g., SACH, uniaxial, multiflex or other K1 /K2 feet) that does not adjust to sloped surfaces and is not self-aligning
7. Has been using a prosthesis for at least 12 months
8. Has had a stable residual limb for at least 3 months (i.e. stable in volume and without cuts or wounds)
9. Is willing to trial a new prosthesis for a 12-week period (if allocated to intervention arm)
10. Is able to self-complete the English language outcome measure tools (or complete with assistance)
11. Is able to follow the detailed verbal instructions required for the functional/clinical tests
12. Is willing to have their GP informed of their involvement in the study
13. Is able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Total final enrolment
55

Key exclusion criteria
A patient will be excluded for the following reasons:
1. Has contraindications of wearing their current prosthesis (e.g., open wound, infection)
2. Has contraindications of wearing the novel prosthesis according to manufacturer's instructions (i.e., a long residual limb - intact side measurement from mid patella tendon to ground minus the socket measurement from mid patella tendon to distal end of socket female-pyramid-adaptor should be at least 115mm)
3. Has had a recent cerebrovascular event, such as a stroke
4. Has a disease that severely affects their memory, such as dementia or Alzheimer's

Date of first enrolment
01/05/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hull & East Yorkshire NHS Trust
United Kingdom
HU16 5JQ

Study participating centre
Nottingham University Hospitals NHS Trust
United Kingdom
NG5 1PJ

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
United Kingdom
PR2 9HT

Sponsor information

Organisation
Hull & East Yorkshire NHS Trust

Sponsor details
Castle Hill Hospital
Office 13, 2nd Floor
Daisy Building
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20029

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol article	protocol	20/09/2019	06/01/2021	Yes	No
Results article	Qualitative experience	18/03/2021	22/03/2021	Yes	No
Other publications		23/04/2023	24/04/2023	Yes	No
HRA research summary			28/06/2023	No	No