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Clinical investigation of the performance and safety of ProsFit original prosthetic sockets

Submission date
12/02/2015

Recruitment status
No longer recruiting

Registration date
17/03/2015

Overall study status
Completed

Last Edited
03/01/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether the new ProsFit Original sockets are as comfortable and functional as participants' existing sockets made using traditional methods and materials.

Who can participate?
Below-knee amputees aged 18 or over from Preston Specialist Mobility Rehabilitation Centre, who can walk without walking aids (frames, crutches or sticks), and five high-intensity users who are involved more actively in jogging and running

What does the study involve?
Participants are involved for 5-6 weeks with 4-6 visits, depending on fitness, ability, availability and progress through the study. Each participant undergoes a medical examination. The SMRC physical training instructor also carries out a fitness assessment including training in using the treadmill. During visits 3 to 6 the sockets are covered so that participants do not know which socket is their current socket and which is the ProsFit socket. There are six phases of mobility testing within the study. The participant starts with Phase 1 and can progress through the phases to the best of their abilities within the time available during visits, with each visit expected to last about 2 hours. In Phase 1 participants' mobility is assessed on the treadmill. Participants are also asked to provide feedback on comfort and if they are experiencing any pain. In Phase 2 participants' mobility is assessed on slopes, again on the treadmill. Again, they are also asked to provide feedback. In Phase 3, still indoors, participants walk between parallel bars, and then outside parallel bars. After this they go outside and walk on a test track (tactile paving, curbs and stairs), simulating real world use. Phase 4 is for the high-intensity users only. This involves running on the treadmill. Phase 5 focuses on activities of daily living, and participants are asked to undertake some basic household tasks. Phase 6 involves gait analysis. At the end of each visit participants' existing sockets are re-connected and re-aligned. At the end of the last visit participants are invited to answer an optional questionnaire about participation in the study.

What are the possible benefits and risks of participating?
The benefits may include personal satisfaction and interest linked with involvement in investigation of a new socket technology. Risks are not significant, as the device has been tested

for structural strength prior to investigation, the Alter-G treadmill with safety harness is used in the first phases of activity testing, and there is consistent monitoring by fully trained and experienced professional prosthetists.

Where is the study run from?
Specialist Mobility Rehabilitation Centre, Preston (UK)

When is the study starting and how long is it expected to run for?
January 2015 to March 2015

Who is funding the study?
ProsFit Technologies UK Ltd

Who is the main contact?
Mr Christopher Hutchison

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

162635

ClinicalTrials.gov number

Secondary identifying numbers
IRAS: 162635, PFTUK150001CIP

Study information

Scientific Title
Clinical Investigation with 12-15 below-knee amputees to test the performance and safety of ProsFit Original Prosthetic Sockets, including blinded RCT comparison to the amputees' own existing prosthetic sockets

Study objectives
Primary hypotheses: There will be no change:
1. in physical integrity of the ProsFit Original prosthetic sockets over the course of use in the clinical investigation. Following this investigation, some additional, laboratory-based, structural testing of the devices will be conducted, independently of the participants.
2. in the participants' experience when using ProsFit Original prosthetic sockets compared to their own traditionally manufactured sockets (by subjective outcome measures such as socket-comfort score, TAPES, EQ-5D-5L, Visual analogue score (pain))

Secondary hypothesis: There will be no change:
3. in participants' ability to walk during the given times, when using ProsFit Original prosthetic sockets compared to their own traditionally manufactured sockets.
4. in participants' natural walking (gait) speed when using ProsFit Original prosthetic sockets compared to their own traditionally manufactured sockets.
5. in the participant's quality of gait, as assessed by the prosthetist of the Investigating team, when using ProsFit Original prosthetic sockets compared to their own traditionally manufactured sockets.
6. in the weight of the ProsFit Original prosthetic sockets compared to the participants' own traditionally manufactured sockets.
7. in the overall performance and safety of the ProsFit Original prosthetic sockets compared to the participants' own traditionally manufactured sockets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 19/12/2014, ref: 14/SC/1373

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Prosthetic sockets for below-knee amputees

Interventions
Amputees are fitted with either ProsFit Original prosthetic sockets or their own existing socket, attached to their standard prosthesis. The patients then are monitored as they carry out a number of phases of mobility testing, and provide feedback.

A prosthetic socket is externally-applied as the container in which the amputee's residual limb (residuum) is embedded, and attached to the prosthesis assembly (collectively: prosthesis).

Each participant will undergo a medical and fitness assessment including training in using the Alter-G ('anti-Gravity') Treadmill. Each participating patient (with informed consent) will be fitted with a ProsFit Original prosthetic socket.. Their own traditionally manufactured socket is also used as a comparator (randomized, single-blind). There are 6 Phases of mobility testing in the protocol.

Intervention Type
Device

Primary outcome measure
Physical integrity of the ProsFit Original prosthetic socket over the course of use in the clinical investigation, as determined by the prosthetist according to standard clinical inspection (no device deficiencies or failures during use, or signs of impending deficiencies or failures). Socket comfort score, TAPES, EQ-5D-5L, Visual analogue score (pain).

In Phase 1: socket inspection, socket comfort score, visual analogue score and PCI are measured at the end of every stage within the phase (approximately every 5 minutes until complete, for total 10 stages).
In Phase 2: socket inspection, socket comfort score, and visual analogue score are measured at the end of every stage within the phase (approximately every 3 minutes until complete, for total 20 stages).
In Phase 3: socket score and visual analogue score are measured at the end of every stage within the phase (approximately every 3 minutes until complete, for total 6 stages). The 2 min walk test, 6 min walk test, and berg balance score are measured once during this Phase, during stage 2.
In Phase 4: (high intensity users only), socket comfort score and visual analogue score are measured at the end of every stage within the phase (approximately every 5 minutes until complete, for total 8 stages).
In Phase 5: socket comfort score, visual analogue score, Barthels index, TAPES, EQ 5D 5L, AMPnoPRO are measured at the end of every stage within the phase (at the end of every ADL,

for total 6 ADLs).
In Phase 6: the gait test is measured/analysed once in this phase.

Secondary outcome measures
PCI, AMPnoPro, 2 min. walk test, 6 min. walk test, gait test, timed continuous walking, and berg balance score. Outcome measures will be taken at specific intervals (see primary outcome measures field).The questionnaires and outcome measure that are not self-questionnaires will be administered by a member of the team.

Overall study start date
06/10/2014

Completion date
14/03/2015

Eligibility

Key inclusion criteria
1. Amputee with trans-tibial amputation
2. Aged 18 years or above
3. Patient of SMRC
4. Activity Level Special Interest Group in Amputee Medicine (SIGAM) grade E or F (no significant limitations on walking distance, no use of walking aids, able to walk up shallow slopes and climb stairs, near normal gait or normal gait)
5. Willing and able to attend the planned research Visits, giving full attempt to adhere to the Investigation protocol in good faith (the patient may withdraw from the study at any point, without necessarily providing any reasons for doing so)
6. Willing and able to provide informed consent
7. Has a prosthesis that allows for its components to be disconnected from the traditional socket and then to be connected to the ProsFit Original prosthetic socket, and reconnected back, for the purposes of the research (connecting and reconnecting done by the prosthetist of the investigation team)
8. Uses an appropriate roll-on liner (this is worn between the residuum and the socket for cushioning and prosthesis suspension purposes) and is willing to use it during the Investigation
9. Willing to also use their own socket (non-ProsFit) as a comparator
10. Patient is expected to attend the clinic before and/or during the period in which the clinical investigation is taking place
11. No conflicts of interest related to participation or the results of the Investigation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
12 - 15

Key exclusion criteria
1. Pre-existing medical conditions that might put the patient at risk or lead to a failure to complete the study. This includes diabetes, ischaemic heart disease (angina), epilepsy, skin conditions that might lead to skin breakdown such as Ehlers-Danlos Syndrome, chronic obstructive airway disease.
2. Current acute medical conditions such as skin infections, stump sores / blisters or recent trauma to the stump
3. Under 18
4. Mental health disorders that may lead to difficulties with participation or understanding protocol

Date of first enrolment
01/01/2015

Date of final enrolment
15/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Specialist Mobility Rehabilitation Centre
Preston
United Kingdom
PR2 8DY

Sponsor information

Organisation
ProsFit Technologies UK Ltd.

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M2 7PW

Sponsor type
Industry

Website
www.prosfit.com

Funder(s)

Funder type
Industry

Funder Name
ProsFit Technologies UK Ltd

Results and Publications

Publication and dissemination plan
The trialists' plans are to publish summary and analyses of study results in relevant peer-journal (s), indicatively around June – September 2015. The study results and analyses will then further be disseminated in conferences and published articles, indicatively at least during the balance of 2015 and 2016. Results may also be disseminated by other means, such as inclusion in reports and articles published on the internet, again indicatively at least during the balance of 2015 and 2016.

Intention to publish date
01/06/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No