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Transtibial prosthetic system design and benefits for the amputee, service providers and society: an evidence based clinical study

Submission date 22/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/04/2005	**Overall study status** Completed	
Last Edited 07/01/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.action.org.uk/research_projects/grant/233/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AP0985

Study information

Scientific Title

Study objectives
Comparative evaluation of two types of prosthetic transtibial socket leading to better understanding of what constitutes a good socket design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 07/01/2010: Granted ethical approval by the Local Regional Health Authority and University Ethics Committees (ref EC/03/S/66)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Transtibial amputation

Interventions
Two groups of patients will each be randomly selected from among those amputees with one of the two socket types under assessment.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Measured pressure distribution, patient activity level and patients opinion elucidated by validated questionnaire for two socket concepts.

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/04/2004

Completion date
04/04/2007

Eligibility

Key inclusion criteria
Established amputees previously fitted with hand cast or pressure cast prosthetic sockets.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
05/04/2004

Date of final enrolment
04/04/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

NCTEPO
Glasgow
United Kingdom
G4 0LS

Sponsor information

Organisation
University of Strathclyde (UK)

Sponsor details
16 Richmond Street
Glasgow
Scotland
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G1 1XQ

Sponsor type
University/education

Website
http://www.strath.ac.uk/

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009		Yes	No