

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
Registration date 14/04/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/01/2010	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

Scotland

Study participating centre

NCTEPO

Glasgow

United Kingdom

G4 0LS

Sponsor information**Organisation**

University of Strathclyde (UK)

ROR

<https://ror.org/00n3w3b69>

Funder(s)

Funder type

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes