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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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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)

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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