

Ankle-foot orthoses by laser-scanning or existing methods

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
4060

Study information

Scientific Title
A randomised interventional treatment trial of the production of ankle-foot orthoses by laser scanning or existing methods in patients referred for rigid and hinged orthoses

Acronym
ABLE

Study objectives

The trial tests new technologies for producing ankle-foot orthoses (AFOs). AFOs are externally applied splints, usually customised to the particular needs of patients, the majority being children with neuromuscular conditions such as cerebral palsy that cause difficulties in controlling movement. The traditional method for producing orthotic devices involves the time-consuming use of plaster of Paris. This method often requires further fitting and adjustment of the orthosis after delivery to the patient.

Laser scanning with computer-aided design and manufacture (LSCAD/CAM) could enable a mould to be created much more quickly, accurately and cheaply once the equipment is purchased, thus helping the NHS to overcome a shortage of skilled orthotists. This technology is used widely in North America but has not yet been used in the NHS or adequately compared to the traditional method. ABLE is a randomised trial to estimate the costs to the NHS and benefits to patients of LSCAD/CAM comparing these with the present approach of creating moulds using plaster of Paris. While laser scanners offer the possibility of large potential benefits, the capital costs of LSCAD/CAM and costs of training orthotists in its use can be a deterrent to its purchase within the NHS. Our Trust provides one of the largest in-house orthotic services in the NHS and has recently acquired the LSCAD/CAM equipment.

If successful, the laser scanning system could be used for all types of orthoses currently produced by the traditional plastering method (e.g., spinal braces, head and neck orthoses, insoles and foot orthoses). A scanner may remove the need for return visits for re-casting because growth can be scaled into the first virtual cast and renewal orthoses can be sent by post. This technology could lead to greater integration and effectiveness of services at specialist orthotic centres where multidisciplinary teams can provide a strong clinical lead to the benefit of many patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands REC Board approved on the 15/08/2007 (ref: 07/Q2604/85)

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

The intervention will include the production of a plaster cast and a virtual moulding using laser scanning with computer aided design and manufacture. Participants will experience both the plaster casting and scanning methods before being randomly allocated to have their AFO made from one of the two methods. The total duration of treatment is one of the outcomes of the study. The total duration of the study follow up is twelve months.

Study entry: single randomisation only

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Time from referral to delivery of ankle-foot orthoses

Key secondary outcome(s)

Health service and societal costs from referral for AFO to 12 months

Completion date

31/12/2009

Eligibility

Key inclusion criteria

All patients up to 21 years of age, either sex, referred for rigid and hinged ankle-foot orthoses

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Do not consent to the study
2. Considered by the orthotist to be unsplintable
3. Unable to communicate directly or via a parent/carer
4. The AFO requested is the Saltiel type

Date of first enrolment

26/02/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust

Shropshire

United Kingdom

SY10 7AG

Sponsor information

Organisation

Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust (UK)

ROR

<https://ror.org/030mbcp39>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Results and Publications

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	01/04/2016		Yes	No