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Ankle-foot orthoses by laser-scanning or existing methods

Submission date	Recruitment status	[ ] Prospectively registered
29/04/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Time from referral to delivery of ankle-foot orthoses

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

Overall study start date
26/02/2008

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

Age group
Other

Sex
Both

Target number of participants
Planned sample size: 150; UK sample size: 150

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
England

United Kingdom

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic and District Hospital NHS Trust
Shropshire
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SY10 7AG

Sponsor information

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

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Sponsor type
Not defined

Website

http://www.rjah.nhs.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

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	01/04/2016		Yes	No