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Effect of custom orthoses on foot pain and plantar pressure in pes cavus

Submission date	Recruitment status	[ ] Prospectively registered
29/03/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/10/2008	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Persons with pes cavus commonly report foot pain, but rigorous scientific
evidence for the effectiveness of custom foot orthoses for this condition is lacking. We aimed to determine the efficacy of custom foot orthoses for pes cavus, with respect to pain relief, reduction of disability and
improvement of plantar pressure distribution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Pes cavus

Interventions
Patients are randomised to one of two groups:
1. Group 1 is treated with custom moulded foot orthoses
2. Group 2 is given sham orthoses

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Foot pain

Secondary outcome measures
Disability

Overall study start date
01/12/2003

Completion date
31/05/2005

Eligibility

Key inclusion criteria
Men and women aged 18 years or older, literate in English to complete health status questionnaires, musculoskeletal foot pain of at least one month duration, bilateral pes cavus and willingness to consent to randomization and study orthoses provisions.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
154

Key exclusion criteria
Use of ankle-foot-orthoses (AFO) and pregnancy.

Date of first enrolment
01/12/2003

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
Australia

Study participating centre

School of Physiotherapy
Lidcombe, NSW
Australia
1825

Sponsor information

Organisation
The University of Sydney - School of Physiotherapy (Australia)

Sponsor details
P.O. Box 170
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Sponsor type
University/education

ROR
https://ror.org/0384j8v12

Funder(s)

Funder type
Charity

Funder Name
Prescription Foot Orthotic Laboratory Association, Australian Podiatry Education and Research Foundation, New South Wales Podiatrists Registration Board

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	01/05/2006		Yes	No