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A randomised controlled trial to estimate the clinical and cost-effectiveness of four different methods of mechanical support in severe ankle sprains

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
16/01/2020

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
HTA 01/14/10

Study information

Scientific Title
A randomised controlled trial to estimate the clinical and cost-effectiveness of four different methods of mechanical support in severe ankle sprains

Acronym
CAST

Study objectives
To estimate:
1. The clinical effectiveness of three different methods of ankle support (below knee plaster cast, Kendall ankle support, Bledsoe boot) in comparison to Tubigrip in the recovery of mobility and function after Grade II and III sprains of the ankle joint.
2. The cost-effectiveness of the three different methods of ankle support in comparison to Tubigrip only. The economic analysis will be conducted from a societal perspective.

Tubigrip has been chosen as the reference (status quo) treatment; it is the cheapest, but is likely to be least effective (ref 1). The Bledsoe boot is a factor of 30 times more expensive (US$50 usual, assuming no re-use), and its clinical effectiveness is yet to be proven. The below knee plaster cast will be Scotch Cast (cost £5). There are a range of ankle supports available. We have selected the Kendall Gel Brace (£19 per brace), which is the cheapest and, in our experience is as clinically effective as other brands. All treatments will be provided in the NHS, in a manner consistent with current national practice.

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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Injury, occupational diseases, poisoning: Musculoskeletal injury

Interventions
1. Below knee plaster cast
2. Kendall ankle support
3. Bledsoe boot
4. Tubigrip

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
Not provided at time of registration.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
17/05/2006

Eligibility

Key inclusion criteria
Patients with Grade II and III sprains of the ankle joint.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
18/11/2002

Date of final enrolment
17/05/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

School of Health & Social Studies
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	14/02/2009		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	case study results	14/01/2020	16/01/2020	Yes	No
Protocol article	protocol	13/01/2005		Yes	No