

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

☐ Prospectively registered

☒ Protocol

Registration date

25/04/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

16/01/2020

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Matthew Cooke

Contact details

School of Health & Social Studies

University of Warwick

Coventry

United Kingdom

CV4 7AL

+44 024 76 575850

m.w.cooke@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

18/11/2002

Completion date

17/05/2006

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

650

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

England

United Kingdom

Study participating centre

School of Health & Social Studies

Coventry

United Kingdom

CV4 7AL

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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?
Protocol article	protocol	13/01/2005		Yes	No
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