

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 16/01/2020	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<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**  
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?
<a href="#">Results article</a>	results	14/02/2009		Yes	No
<a href="#">Results article</a>	results	01/08/2010		Yes	No
<a href="#">Results article</a>	case study results	14/01/2020	16/01/2020	Yes	No
<a href="#">Protocol article</a>	protocol	13/01/2005		Yes	No