

# Valgus knee bracing for medical compartment osteoarthritis (OA)

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/08/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
N0436151092

## Study information

**Scientific Title**

**Study objectives**

The aim of this project is to ascertain the improvements in function and pain in patients with osteoarthritis of the knee, using valgus offloading knee braces. These braces are currently used for osteoarthritis within the department of orthopaedics in Leeds by some surgeons, however we do not have a prospective controlled trial to determine the benefit, if any, of using the braces available to us.

**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)**

Treatment

**Health condition(s) or problem(s) studied**

Musculoskeletal Diseases: Osteoarthritis of the knee

**Interventions**

Questionnaire; Randomised controlled trial

30/08/2012: Please note that this trial was abandoned before starting due to a lack of funding

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The patients will be assessed using one of the most internationally validated scoring systems, the WOMAC score, and also a Visual Analogue Pain Scale

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

21/11/2005

**Reason abandoned (if study stopped)**

Lack of funding/sponsorship

**Eligibility**

**Key inclusion criteria**

The patients will be selected from new patient referrals seen in the orthopaedic outpatient clinic under Mr Calder at Leeds General Infirmary. They will be patients diagnosed with knee arthritis. If they fulfil the inclusion criteria then they will be given the option of taking part in the study and be consented accordingly.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Previous knee surgery in last 12 months
2. Arthritis other than OA
3. Hip disease
4. Previous tibial/femoral fracture
5. Morbid obesity BMI>35 (difficulty in brace fitting)
6. PVD or skin disorder preventing brace use

**Date of first enrolment**

21/06/2004

**Date of final enrolment**

21/11/2005

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Orthopaedic Surgery

Leeds

United Kingdom

LS9 7TF

**Sponsor information**

**Organisation**

Department of Health

**Funder(s)****Funder type**

Government

**Funder Name**

Leeds Teaching Hospitals NHS Trust (UK)

**Funder Name**

NHS R&D Support Funding

**Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration