

Valgus knee bracing for medical compartment osteoarthritis (OA)

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Simon Boyle

Contact details

Orthopaedic Surgery
Leeds Teaching Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)7739 490649

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