

Valgus knee bracing for medical compartment osteoarthritis (OA)

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 30/08/2012	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 use 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

21/06/2004

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

Age group

Adult

Sex

Both

Target number of participants

20

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

England

United Kingdom

Study participating centre

Orthopaedic Surgery

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

Department of Health

Sponsor details

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79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)**Funder type**

Government

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

Funder Name

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