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Do knee braces or foot insoles help pain and function in patients with knee osteoarthritis?

Submission date	Recruitment status	[ ] Prospectively registered
22/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/03/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/01/2013	Musculoskeletal Diseases	

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
N/A

Study information

Scientific Title
Biomechanical assessment of medial compartment knee osteoarthritis before and after surgery

Study objectives
1. There is no significant difference in the knee kinematics or kinetics in patients with medial compartment knee osteoarthritis when wearing the valgus knee brace or lateral wedged insole
2. There is no significant difference in the clinical outcome scores in patients with medial compartment knee osteoarthritis when wearing the valgus knee brace or lateral wedged insole
3. There is no significant difference in the knee kinematics or kinetics or clinical scores between the two treatments (valgus knee braces and lateral wedged insoles)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Stockport Local Research Committee. Date of approval: 01/12/2003 (ref: 03/12/2363)
2. Salford and Trafford Local Research Ethics Committee (ref: 03/12/2363)

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Arm 1: A valgus knee brace which is classed as a direct orthotic
Arm 2: A lateral wedged insole which is classed as an indirect orthotic

Cross-over: Two week intervention period and a two-week wash-out period to account for carry-over effects from the first treatment.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
1. Knee adduction moment
2. Knee kinematics and kinetics

These outcomes were assessed at the following timepoints:
T1: Baseline assessment and start of wear of intervention 1
T2. Two weeks following wear of intervention 1
T3. Two weeks after no treatment to deal with carry over effects, and start of intervention 2
T4. Two weeks following wear of intervention 2

Secondary outcome measures
1. Western Ontario and McMaster Osteoarthritis Index (WOMAC), Pain and Function Subscales
2. Knee Pain Visual Analogue Scale (VAS) (0 = no pain, 10 = extreme pain)

These outcomes were assessed at the following timepoints:
T1: Baseline assessment and start of wear of intervention 1
T2. Two weeks following wear of intervention 1
T3. Two weeks after no treatment to deal with carry over effects, and start of intervention 2
T4. Two weeks following wear of intervention 2

Overall study start date
01/03/2003

Completion date
01/10/2006

Eligibility

Key inclusion criteria
1. Male and female between 45 and 75 years of age
2. Medial compartment knee osteoarthritis symptoms
3. Diagnosis confirmed on radiographs
4. Able to walk and stand on one leg for about three seconds

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
28

Key exclusion criteria
1. Previous knee pain or any other musculo-skeletal conditions
2. Currently wears orthoses of any description prescribed by a podiatrist or orthotist
3. Tricompartmental knee osteoarthritis and/or clinical evidence of patellofemoral disease or knee pathology (other than medial compartment osteoarthritis) likely to be causing their knee pain
4. Unable to walk unsupported or stand on affected leg for 3 seconds
5. Severe coexisting medical morbidities

Date of first enrolment
01/03/2003

Date of final enrolment
01/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Room PO18
Salford
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.salford.ac.uk

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
University/education

Funder Name
University of Salford (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?
Results article	results	01/03/2013		Yes	No