# 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 [ ] Statistical analysis plan Registration date Overall study status 03/03/2008 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 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

Protocol serial number

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

### Study type(s)

Treatment

# 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(s)

- 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

### Key secondary outcome(s))

- 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

### 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

### Healthy volunteers allowed

No

### Age group

Adult

#### Sex

Αll

### 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

United Kingdom

England

Study participating centre Room PO18

Salford United Kingdom M6 6PU

# Sponsor information

### Organisation

University of Salford (UK)

**ROR** 

https://ror.org/01tmqtf75

# Funder(s)

# Funder type

University/education

#### **Funder Name**

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

Participant information sheet 11/11/2025 No Yes