

The effectiveness of a lateral wedge insole on osteoarthritis pain, activity level and joint loading

Submission date 19/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/06/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/10/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis (OA) is a condition that causes the joints to become painful and stiff. People with knee OA suffer from pain during normal activities such as walking, standing or climbing stairs, so they reduce their overall activity in order to minimise the pain. Using lateral wedge insoles in their shoes can reduce patients' pain by decreasing the weight which is transmitted through their knee joint. The aim of the study is to find out whether a lateral wedged insole improves activity levels in patients with medial knee OA.

Who can participate?

Participants aged 40-85 suffering from OA and on the waiting list for surgery.

What does the study involve?

Participants with knee OA will be randomly allocated into two groups, to wear either lateral wedged insoles or neutral insoles for six weeks. Knee loading, level of physical activity, knee pain, physical function and balance will be measured.

What are the possible benefits and risks of participate?

There will be no immediate direct benefits to those taking part as the result will help future practice with insoles. However, wearing insoles for six weeks may decrease knee pain and increase comfort when walking. There are no risks with using insoles or during the study. Using the activPAL device (to monitor the level of physical activity) is completely safe as this has been used many times previously and it is comfortable to wear for the participants.

Where is the study run from?

The study will be performed in the gait laboratory at the University of Salford (UK).

When is the study starting and how long is it expected to run for?

From May 2015 until June 2016.

Who is funding the study?

1. University of Salford (UK)
2. King Saud Medical City (Saudi Arabia)

Who is the main contact?

Professor Richard Jones, r.k.jones@salford.ac.uk
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

062015

Study information

Scientific Title

The effectiveness of a lateral Wedge insole on osteoarthritis Pain, Activity level and joint Loading: a pilot study

Acronym

WPAL Study

Study objectives

The external knee adduction moment (knee loading) will decrease in the group using the lateral wedged insole. Whereas, level of physical activity, knee pain, dynamic balance, and physical function will improve in the group using the lateral wedged insole. In addition, it is hypothesised that reduction in knee loading will lead to a corresponding increase in activity level in comparison to the comparator group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethical Approval Panel, the University of Salford, 04/06/2014, ref: HSCR14/24
2. NHS ethics approval: not provided at time of registration.

Primary study design

Interventional

Study design

Randomised pilot study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Medial knee osteoarthritis

Interventions

Patients are randomised to two groups: lateral wedged insole group, and neutral insole group. Participants will wear those insoles for six weeks

Intervention Type

Device

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lateral wedge insole

Primary outcome(s)

1. Level of physical activity
2. External knee adduction moment (EKAM)
3. Pain level

Outcomes will be measured in four different specific period of time (pre- intervention, baseline, during intervention, post-intervention) to find out any change in these outcomes compare to the baselines findings.

Key secondary outcome(s)

1. Dynamic balance
2. Knee injury and Osteoarthritis Outcome Score (KOOS) other items
3. Physical Activity Score for the Elderly (PASE)
4. Aggregated Locomotor Function (ALF) score
5. 12-item Short-Form Health Survey (SF-12)

Completion date

30/06/2016

Eligibility

Key inclusion criteria

1. Age 40-85
2. Pain with walking.
3. Participants have been diagnosed with mild-moderate medial knee OA by GP based on the clinical and radiographic criteria
4. On AP or PA view x-ray (weight bearing, if possible) within the last 2 years of screening. Therefore, for a patient to be eligible on x-ray they must fulfil the following criteria
 - 4.1. KL grade 2 or 3 in the tibiofemoral joint (TFJ)
 - 4.2. The KL grade in the TFJ must be higher than the PFJ and cannot be equal
 - 4.3. The medial joint space narrowing score must be higher than the lateral joint space narrowing score and cannot be equal
5. Medial tenderness. Absence of PF tenderness on examination.
6. They are able to walk for 100 metres non-stop - participant response.
7. Can walk without any walking aid.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

20

Key exclusion criteria

1. A history of high tibial osteotomy or other realignment surgery or total knee replacement on the affected side
2. Knee Arthroscopy with the last 6 months
3. Intra-articular injection into the treatment knee in the last 3 months.
4. Inflammatory arthritis including Rheumatoid Arthritis
5. Complex pain conditions such as fibromyalgia
6. Any foot and ankle problems
7. Severe coexisting medical morbidities,
8. Use, or have used, orthoses within the last 2 months.
9. BMI >35 since gait laboratory cannot perform accurate measurements.
10. Unable to walk unaided.

If the participants cannot walk for 100 metres without stopping they will also be excluded, as they may be unable to complete the full testing protocol.

Date of first enrolment

01/05/2015

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

PO36 Brian Blatchford Building

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)

Funder Name

King Saud Medical City (Saudi Arabia)

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?
Results article	results	01/04/2017	26/10/2020	Yes	No