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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

Registration date
29/06/2015

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 staring 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised pilot study

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 contact the principle investigator to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/05/2015

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 that 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

Age group
Adult

Sex
Both

Target number of participants
30 participants with medial knee OA.

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
England

United Kingdom

Study participating centre
PO36 Brian Blatchford Building
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Sponsor information

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Sponsor type
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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

Publication and dissemination plan
Not provided at time of registration

2018 results in thesis http://usir.salford.ac.uk/id/eprint/43818/ (added 26/10/2020)

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	01/04/2017	26/10/2020	Yes	No