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Effect of lateral wedge insoles on osteoarthritis knee pain and joint loading

Submission date
08/08/2013

Recruitment status
Stopped

Registration date
08/08/2013

Overall study status
Stopped

Last Edited
16/03/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee pain on the inside of the joint is associated with a condition called medial knee osteoarthritis. An individual's walking gait can affect the stress that is distributed to this side of the joint and conservative treatments aim to reduce this stress. A number of shoes or shoe insoles have been designed to lower these stresses and could be extremely popular, effective and inexpensive interventions for this disease. However, whilst the interventions have shown positive reductions in this stress, recent findings have identified that 39% of patients did not have a reduction in knee stress when wearing one of these devices (a lateral wedge insole, which is a foot-worn insole with one edge higher than the other) and are therefore classified as biomechanical non-responders. It is thought that this may be one of the reasons why studies so far have failed to show good clinical evidence for their treatment. The patients who did have a large reduction are classed as biomechanical responders and it is thought that clinical findings would be better if we only focused on these patients. The aim of this study is to assess the effect of lateral wedge insoles on osteoarthritis knee pain and joint loading.

Who can participate?
Patients aged 40-85 with medial knee osteoarthritis

What does the study involve?
Patients undertake a test where their response to a lateral wedge insole is assessed. If they are deemed a responder they join the study and wear two different insoles (a lateral wedge insole or a neutral insole) for a period of 6 weeks each, with a 4-week break between the two periods. Participants' pain is assessed at the start of the study and at weeks 3, 6, 10, 13 and 16.

What are the possible benefits and risks of participating?
It is very unlikely that there are any side effects of the insoles, although the amount of walking can cause some discomfort.

Where is the study run from?
University of Salford (UK)

When is the study starting and how long is it expected to run for?
June 2013 to October 2014

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Helen Williams
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
14957

Study information

Scientific Title
Effect of lateral wedge insoles on osteoarthritis knee pain and joint loading: the WEDGE study

Acronym
WEDGE

Study objectives
The management of individuals with knee osteoarthritis remains a challenge, especially for younger patients or those who do not require surgery. As osteoarthritis is a mechanically driven disease in which the disease is often caused by changes in loading. Therefore, conservative interventions, such as insoles, which aim to reduce the loads at the knee, would be a welcome treatment. However, many studies have not consistently found improved pain in the knee when wearing insoles.

Ethics approval required

Old ethics approval format

Ethics approval(s)
13/NW/0362; First MREC approval date 22/05/2013

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Responders vs non-responders, The treatment first group A will be given the pair of lateral wedge insoles (insert A) (which reduced the medial load and was comfortable) for 6 weeks. After a 4 week washout period, this group will then crossover to the non-treatment (own shoes with neutral insert B) condition and will return at 16 weeks The treatment second, group B, will be given the non-treatment first (own shoes with neutral insert (B)) and asked to return at 6 weeks after which they will enter the was

Follow Up Length: 4 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Knee injury and Osteoarthritis Outcome Score (KOOS) pain scale, measured at baseline, weeks 3, 6, 10, 13 and 16

Key secondary outcome(s)
1. Comfort rating scale, measured at baseline, weeks 3, 6, 13 and 16
2. External adduction moment, measured at 2 weeks (evaluation of responder/non-responder status), 6 weeks and 16 weeks
3. Patient perceived global change in pain, measured at baseline, week 6, 10 and 16

Completion date
30/10/2014

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Aged 40 to 85 years
2. Pain with walking (using KOOS question (P5), they need to have at least mild pain walking on a flat surface)
3. On anteroposterior (AP) or Posterior-Anterior (PA) view x-ray (weight bearing, if possible) within the last 2 years of screening. They need to have definite medial narrowing and not lateral narrowing and evidence (osteophyte + or definite sclerosis) of OA (this would give them Kellgren and Lawrence grade 2 or 3 with medial narrowing). And the absence of patellofemoral osteoarthritis on x-ray (must be less severe OA that medial disease and cannot be KL3 or higher in patellofemoral joint). Therefore for a patient to be eligible on x-ray they must fulfil the following criteria:
3.1. KL grade 2 or 3 in the tibiofemoral joint (TFJ)
3.2. The KL grade in the TFJ must be higher than the PFJ and cannot be equal
3.3. The medial joint space narrowing score must be higher that the lateral joint space narrowing score and cannot be equal
3.4. Medial tenderness either by their own indication that this is where they have pain or by examination showing tenderness at the medial TF joint line Clinical diagnosis by qualified clinician. Absence of of PF tenderness on examination
3.5. They are able to walk for 100 metres non-stop
Target Gender: Male & Female; Upper Age Limit 85 years ; Lower Age Limit 40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Participants will be excluded if the pain is more localised to the patellofemoral joint on examination than medial joint line, have tricompartmental knee osteoarthritis or have grade 4 medial tibiofemoral osteoarthritis on the Kellgren Lawrence scale.

Other exclusions include:
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. Intraarticular injection into the treatment knee in the last 3 months
4. Inflammatory arthritis including Rheumatoid Arthritis
5. Complex pain conditions such as Diabetic Neuropathic pain, fibromyalgia
6. Any foot and ankle problems that will contraindicate the use of the footwear load modifying interventions.
7. Severe coexisting medical morbidities
8. Use, or have used, orthoses of any description prescribed by a Podiatrist or Orthotist within the last 2 months.
9. Cannot understand procedures

10. Body Mass Index (BMI) >35 since gait laboratory cannot perform accurate measurements
11. Unable to walk unaided and have to rely on a stick, crutch or frame
12. 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
01/10/2013

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Salford
Gait Laboratory
Brian Blatchford Building
Centre for Health, Sport and Rehabilitation Sciences Research
Salford
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M6 6PU

Sponsor information

Organisation
University of Salford (UK)

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (formerly ARC Arthritis Research Campaign); Grant Codes: MP/18676

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The trial design underwent significant design changes (inclusion of extra imaging outcomes), resulting in the trial having to be restarted using a new name. The superseding trial was named the IN RESPOND trial. Please see this trial record entry for further details (http://www.isrctn.com/ISRCTN55059760).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No