

Clinical trial of insoles for pain at the front of the knee

Submission date 23/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/05/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
CT223

Study information

Scientific Title

A randomised controlled trial to evaluate the effectiveness of insoles to treat anterior knee (patella femoral) pain

Acronym

KP Trial

Study objectives

Knee pain remains a significant burden to a large proportion of the population. It has a multifactorial etiology and diagnosis is often non specific. Anterior knee pain (patellofemoral pain syndrome) has been described as the most prevalent disorder of the knee. The cause of the condition is not clearly understood and the cause of pain may not be the same for each person. Hence a variety of treatment regimes (devices) are employed for the treatment of the condition. Citizens are likely to seek their own approaches to managing knee pain prior whilst waiting for, or instead of, seeking advice and remedy from the health services. This trial will seek to evaluate the effectiveness of an in shoe type of orthosis in the management of anterior knee pain.

Hypothesis: a functional insole will produce greater improvements in knee pain compared to a sham control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee, University of Salford, 12/03/2008, ref: 07/054

Study design

Randomised subject-blinded single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

Anterior knee pain

Interventions

The participants will be randomly allocated to the following two arms:

1. Arm 1: Orthaheel® regular. This is a 3/4 length insole with arch shape. It is inserted into shoes and worn daily for 12 months
2. Arm 2: Sham control insole. This is a full length 3 mm deep soft flat insole. It is inserted into shoes and worn daily for 12 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Knee pain
2. Knee function

The outcomes above will be measured using the following at 4 weeks:

- a. VAS (scores 0-10)
- b. The Kujala Anterior knee pain questionnaire

Secondary outcome measures

1. Use of insoles (in time)
2. Knee pain at 3, 6 and 12 months (see primary outcome measures for methods of measurement)
3. Knee function at 3, 6 and 12 months (see primary outcome measures for methods of measurement)

Overall study start date

28/03/2008

Completion date

31/07/2009

Eligibility

Key inclusion criteria

1. Male or female participants between the ages of 18 and 65 years old
2. Participants with self-reported anterior knee pain (pain at the front of the knee) with a minimum of 4 weeks duration
3. Participants with self-reported anterior knee pain who score at least 40 mm on a 100 mm visual analogue scale (VAS) for pain
4. Participants with self-reported anterior knee pain in the 2 days prior to recruitment
5. Participants who agree to wear the insoles provided for at least 4 hours each day and complete diary cards and postal questionnaire as required
6. Participants who give written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients must not report any acute injury to the knee at the onset of their anterior knee pain
2. Patients must not report posterior or medial/lateral knee pain or any secondary pain elsewhere in lower limb joints since the onset of anterior knee pain
3. Patients must not have any significant diagnosed musculo-skeletal disease, such as rheumatoid arthritis, diabetes or osteoarthritis of the knee or deterioration dysfunction of associated structures of the knee e.g., cartilage or any other condition associated with sensory and motor dysfunction
4. Patients must not have received or self administered treatment for the knee pain in the previous 4 weeks
5. Patients who are pregnant or breast-feeding
6. Patients who have received or self-administered treatment for the knee pain in the previous 4 weeks
7. Patients who have received corticosteroid injection therapy in the knee in the previous 3 months
8. Patients that were previously in this study
9. Patients that were in another study within the last 3 months

Date of first enrolment

28/03/2008

Date of final enrolment

31/07/2009

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Director**

Salford

United Kingdom

M6 6PU

Sponsor information

Organisation

SSL International (UK)

Sponsor details

SSL International Plc

Venus Building

1 Old Park Lane

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M41 7HA

Sponsor type

Industry

Website

<http://www.ssl-international.com>

ROR

<https://ror.org/01g87hr29>

Funder(s)

Funder type

Industry

Funder Name

SSL International (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