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Effects of patellofemoral brace and taping on muscle and knee dynamics

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
26/02/2013

Overall study status
Completed

Last Edited
16/01/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Arthritis behind the knee-cap is more common than we previously thought and its treatment is slightly different from arthritis in other parts of the knee. Putting on a thin knee brace seems to be a helpful treatment and makes people with knee-cap arthritis have less pain, walk better and develop stronger thigh muscles. This may also be true with a simple piece of tape across the knee-cap. Both treatments are inexpensive, simple and risk free ways to ease knee-cap pain caused by arthritis. We are interested to see what effect a knee brace or knee-cap taping has on the position of the knee cap, the knee and the whole leg. While braces and tape are effective in relieving pain for those with knee cap arthritis, their effects on the position of the knee cap are unknown. The brace or tape may work by changing the position of the knee-cap or changing the way the calf, thigh and hip muscles work. But we are still not sure if this is because the brace moves the knee-cap into a different position, changes the way muscles contract, or changes the movement of the whole thigh and leg when doing certain tasks. This study will allow us to understand why braces and tape seem to be successful non- surgical treatments for knee-cap arthritis and help us to direct modifications and new treatment for this common condition. It will compare the effects of a brace and taping with nothing at all on the knee-cap position, muscle activity and knee movement.

Who can participate?
Male and female patients between the ages of 40-70 years with knee-cap arthritis and who participated in our previous studies.

What does the study involve?
The study will involve people with knee-cap arthritis going up and down stairs, to compare the brace and the knee-cap tape with nothing at all and take measurements of the knee and leg movements, knee stresses and muscle activity. We also want information of knee-cap position to see if this is altered by the brace or tape, so we will take advantage of the unique open MRI scanner to get MRIs of the knee with the person standing in 3 conditions: with brace, with tape and with nothing at all. Standing up will give a much more relevant idea of knee-cap and knee position than the normal scan position (lying in).

What are the possible benefits and risks of participating?
The risks of participating are minimal. None of the procedures have high risk. All participants will be asked if they have an allergy to tape prior to application.
Stair descent can be challenging with arthritis and so subjects will wear a safety harness operated by one of the research team. MRI has no known risks. The benefits will be added information about how subjects walk, if they are adopting unusual ways of going up and down stairs and if the brace changes these for the better. They will be given a new brace for the tests which they can take away with them to wear if they find it helpful.

Where is the study run from?
The study will take place in the gait lab and MRI scanner at the Manchester Metropolitan University. It is sponsored by the University of Manchester.

When is the study starting and how long is it expected to run for?
The study took place between April and December 2012.

Who is funding the study?
The study is funded by Arthritis Research UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of a patellofemoral brace and patellar taping on knee movement, muscle activity and patellar position in patients with patellofemoral osteoarthritis (PFOA)

Acronym
BRACE-TWO

Study objectives
There will be changes in the sagittal moments of the knee and lower limb when negotiating stair ascent and descent in participants with knee-cap arthritis when comparing a knee brace, tape across the knee-cap or nothing at all.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Cheshire Research Ethics Committee, 11th January 2012, ref: 11NW/0851

Study design
Observational clinical study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

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
Patellofemoral Osteoarthritis

Interventions
Each patient will be measured with three conditions: firstly, a flexible Lycra knee brace, secondly, a single piece of medical tape applied across the knee-cap, and thirdly, nothing at all. The order of these will be randomised by the study statistician.
We will be observing the effect of the two interventions compared to no intervention by

measuring muscle and joint forces, knee, knee-cap and leg movement in stairs tests and also by MRI scans in lying and standing.
Participants will be seen only on one occasion, which will last two hours.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Kinetic and kinematic lower limb variables and EMG lower limb activity normalised to maximum activity during stair ascent and descent with brace, with tape or with nothing at all (control).
2. Measurements of patellar position in FWB and NWB positions using brace, tape or nothing at all on the knee. Measurements of meniscal extrusion in FWB and NWB positions.

Secondary outcome measures
1. Patellar position done clinically using a novel device and compared to the FWB MRI scans
2. Knee Pain on a 10 cm visual analogue scale (VAS)
3. Brace effectiveness on the Knee Osteoarthritis Outcome Score (KOOS)

Overall study start date
20/04/2012

Completion date
21/12/2012

Eligibility

Key inclusion criteria
All subjects will be invited to participate who have completed the R.O.A.M. BRACE trial which involved treatment with a PF brace and repeated MRIs. Thus, to have participated in the original study subjects needed to be eligible for MRI (see below).
The criteria for the R.O.A.M. BRACE study for PFOA were:
1. Age 40 -70 (upper age limit because of the likelihood of coexistent Tibio-Femoral OA in older years).
2. Patellofemoral pain should be reproduced with stair climbing, kneeling or squatting but not with standing or walking on level ground
3. They should be on a stable medication regimen for 3 months.
4. Participants will be examined on the day on the visit and prior to the testing to assess physical findings in their knee.

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
30

Key exclusion criteria
1. They have previously had a patellar fracture or patellar realignment surgery.
2. Predominant symptoms emanating from the tibiofemoral joint or from meniscal or ligament injury 3. Patient has rheumatoid arthritis or other forms of inflammatory arthritis
4. Intra-articular steroid injection into the painful knee in the six weeks and arthroscopy in the last 3 months.

MRI scan exclusion criteria:
1. Cochlear implants
2. Any metal objects in the body including joint prostheses
3. Cardiac or neural pacemakers
4. Hydrocephalus shunts
5. Intrauterine contraceptive device or coil

Date of first enrolment
20/04/2012

Date of final enrolment
21/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Arthritis Research UK
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
University of Manchester

Sponsor details

Oxford Road
Manchester
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	16/01/2019	Yes	No