ISRCTN96689245 https://doi.org/10.1186/ISRCTN96689245

Patellar taping will reduce pain but will not provide any measurable changes in patellar position from MRI data or from the caliper

Submission date
22/10/2015

Recruitment status
No longer recruiting

Registration date
16/11/2015

Overall study status
Completed

Last Edited
15/08/2019

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
The knee is the largest weight-bearing joint in the body. It is a complex joint where the shin bone (tibia) and thigh bone (femur) meet creating a “hinge”. The kneecap (patella) is a small, triangular shaped bone located in front of the knee joint. It is very important that the patella is in the correct position, as it plays a vital role in helping to bend (flexion) the knee by acting as a “pulley” for the thigh (quadriceps) muscle. Patellar mal-alignment, also known as patellofemoral pain is a common condition in which the patellar does not aligned properly. Normally, when the knee bends, the patellar moves in a small groove in the femur (femoral groove). When the patella is not lined up with this groove, it can travel more to the side, making it rub against the femur. This causes the knee to become overloaded with pressure causing pain when bending the knee. A common treatment for patellar mal-alignment is taping the knee to support the patella (McConnell taping technique). This works by applying the tape to the skin to reposition the patella relative to the femur when the knee is bent up to 30° (30° flexion). It has been found that many patients experience a reduction in pain after this taping is applied, however more research is needed to find out if the tape is actually managing to realign the patella. The aim of this study is to find out whether the McConnell taping technique can realign the position of the patella in an MRI scanner and with a calliper, and whether this will lead to reduced pain during squat activities.

Who can participate?
Adults with pain at the front and center of the knee with patellar mal-alignment.

What does the study involve?
All participants begin the study by having measurements taken of their leg in order to look at the position of the patella when the knee is bent at 30°, using MRI scanning and a custom built calliper (device for measuring distance). They are also asked to complete squatting exercises so that their levels of pain can be measured. These measurements are then repeated in order to ensure that the measurements are valid. Participants are then randomly allocated to one of two groups. Those in the first group have their knee taped using the McConnell taping technique, to support the patella in the correct position. Those in the second group have placebo (dummy)

taping applied, which is not designed to have any effect on their patella positioning. For all participants, the tape is worn for about 20 minutes so the measurements of patella position and pain can be repeated. Those in the corrective taping group will then have the placebo taping applied, and those in the placebo group will have the corrective taping applied.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in pain from the taping. This could help to find better treatments for that individual in future. There are no notable risks of taking part, although participants may feel pain when they are completing the squatting exercises.

Where is the study run from?
London Sports Orthopaedics (UK)

When is the study starting and how long is it expected to run for?
January 2016 to April 2018

Who is funding the study?
1. Buckinghamshire New University (UK)
2. Brunel University London (UK)

Who is the main contact?
Mr Kevin Campbell-Karn
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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
N/A

Study information

Scientific Title
Effects of taping on MRI and a novel caliper measuring patellar mal-alignment and subjective perception of pain in patients with patellofemoral pain (PFP)

Study objectives
1. There will be a reduction in pain during squat activities when patellar taping is applied and when placebo taping is applied when compared to baseline
2. MRI will not display any significant differences in patellar positioning following patellar taping and placebo
3. The MRI patellar positioning will correlate with the patellofemoral calliper data
4. The patellofemoral calliper will have good agreement with the MRI equivalent data
5. The patellofemoral caliper will provide good intratester reliability
6. The patellofemoral caliper will not display any significant differences in patellar positioning following taping and placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the College of Health and Life Sciences, 30/01/2015, ref: RE13-14

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Patellofemoral pain

Interventions
All participants will have baseline measures taken at the start of the visit. These include: MRI of the knee in a fixed 30 degrees of flexion position, VAS measured during a squat activity and measurements taken using the patellofemoral calliper for the location of the knee cap. All participants are then assessed again in order to ensure that no changes occur by chance. Participants are then randomly allocated to one of two groups:

Intervention group: Participants will have McConnell taping applied in accordance with the process to alleviate mal-alignment and will have an MRI, a patellofemoral caliper measurement and a squatting movement to assess pain.

Placebo group: Participants will have sham tape applied to the front of the knee without any correction to the position of the knee cap, again participants will have an MRI, a patellofemoral caliper measurement and a squatting movement to assess pain.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Bisect offset, patellar overhang, congruence angle, sulcus angle, patellar shift, and equivalent position measurements are measured using MRI extracted data tested before and after each intervention
2. Pain measured using visual analogue scale (VAS) before and after each intervention
3. Relative postions of the patella and femur are measured using patellofemoral caliper measurements tested before and after each intervention

Secondary outcome measures
1. Comparisons between the MRI extracted data and the patellofemoral caliper measurements compared after the trials are all completed using MRI data and the mean scores from the caliper
2. Changes in VAS scores measured immediately after interventions correlating to any changes in MRI and caliper measurements

Overall study start date
01/01/2016

Completion date
06/04/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Symptomatic with anterior knee pain
3. Confirmed as having patellar malalignment by an orthopaedic consultant via X-ray

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Vulnerable adults or those unable to make decisions for themselves
2. Under 18 years of age
3. Anyone with metal or other implants containing metals such as pacemakers

Date of first enrolment
16/10/2017

Date of final enrolment
10/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London Sports Orthopaedics
31 Old Broad Street
London
United Kingdom
EC2N 1HT

Sponsor information

Organisation
Brunel University

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Heinz Wolff Building
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UB8 3PH

Sponsor type
University/education

Organisation
Bucks New University

Sponsor details
Queen Alexandra Road
High Wycombe
England
United Kingdom
HP11 2JZ

Sponsor type
University/education

Organisation
Brunel University London

Sponsor details

Sponsor type
Not defined

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

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
University/education

Funder Name
Bucks New University

Alternative Name(s)
Buckinghamshire New University, School of Science and Art, Wycombe Technical Institute, High Wycombe College of Technology and Art, Buckinghamshire College of Higher Education, Buckinghamshire Chilterns University College, BNU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Brunel University London

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This study is intended to be published in peer-reviewed scientific journals. The data will also be shared with the International Patellofemoral Pain research retreat and will be presented at international conferences to the scientific community.

2018 results published in thesis: https://bura.brunel.ac.uk/handle/2438/18284 (added 15/08 /2019)

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available. The data will be stored on a secure server drive at Bucks New University.

IPD sharing plan summary
Not expected to be made available