ISRCTN33399646 https://doi.org/10.1186/ISRCTN33399646

Does exercise help greater trochanter pain syndrome?

Submission date
18/06/2018

Recruitment status
Stopped

Registration date
25/07/2018

Overall study status
Stopped

Last Edited
05/11/2019

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
Greater Trochanter Pain Syndrome (GTPS) is a painful condition affecting the tendons on the outer side of the hip.The most common symptom is pain over the outer thigh, particularly felt when the muscles contract during walking or climbing steps and slopes, but also when lying on the affected side at night. The pain can affect normal daily activities such as walking and sleeping.
Treatment is usually a corticosteroid injection or physiotherapy but we do not know which treatment works best long term. Research into other tendon problems has shown that some types of exercise can ease pain and improve daily activity. This study is to see whether exercise can help patients with GTPS. It is a pilot study that will help us to plan a larger research trial.

Who can participate?
Men or women between the ages of 35 and 70 can take part if they have been referred to physiotherapy for GTPS by their General Practitioner (GP).

What does the study involve?
All participants will have a corticosteroid injection and advice. Half the participants will be randomly selected to do exercises at home and attend five group classes held in a physiotherapy department.
All participants will fill in questionnaires about their activity level and pain at the beginning of the study, after 3 months and 1 year. We will compare the pain and activity of participants having injection and advice with participants who also did exercise.

What are the possible benefits and risks of participating?
There is no extra benefit from taking part. Research like this helps to improve the treatment and care provided to patients with GTPS now and in the future.
The normal risks of treatment apply. Exercise can cause soreness for up to 48 hours but the exercises in the study are designed to reduce the risk of this.
Possible side-effects of corticosteroid injection are a temporary increase in pain, a change in skin colour or a dimple where the injection has been given. These side effects happen occasionally. Less common but more serious side effects include infection, muscle damage or unwanted reaction to local anaesthetic or steroid.

Where is the study run from?
The study is run by the Royal Devon & Exeter Hospital, Devon, UK. Three physiotherapy departments will provide the exercise groups and advice sessions.

When is the study starting and how long is it expected to run for?
The study is expected to start in October 2018 and run for 2 years

Who is funding the study?
The study has been funded by a Physiotherapy Research Foundation project grant. This is part of the Chartered Society of Physiotherapy Charitable Trust.

Who is the main contact?
Alison Smeatham
Alisonsmeatham@nhs.net

Contact information

Type(s)
Scientific

Contact name
Ms Alison Smeatham

Contact details
Hip Research Unit. Royal Devon & Exeter NHS Foundation Trust. Barrack Road.
Exeter
United Kingdom
EX2 5DW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1810689

Study information

Scientific Title
Does the addition of an exercise programme improve outcomes in Greater Trochanter Pain Syndrome compared to corticosteroid injection and advice? A pilot study

Study objectives
To inform the design and methodology of a future randomised controlled trial (RCT) comparing an exercise programme with routine care on the symptoms of greater trochanter pain syndrome (GTPS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted July 2018 to South West UK Research Ethics Committee

Study design
Pilot single-centre single-blind interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Greater trochanter pain syndrome

Interventions
Intervention group: Corticosteroid injection and 5 sessions of group exercise and advice supervised by a physiotherapist plus a home exercise programme
Routine care group: Corticosteroid injection and a single physiotherapy session providing advice on self-management of the condition.

Intervention Type
Mixed

Primary outcome measure
Change in GTPS-related disability assessed using VISA-G questionnaire score at 3 and 12 months

Secondary outcome measures
1. Change in quality of life assessed using EQ-5D questionnaire at 3 and 12 months
2. Change in musculoskeletal symptoms and quality of life assessed using MSK-HQ questionnaire at 3 and 12 months
3. Self-reported assessment of activity level assessed using UCLA questionnaire (Zahiri et al., 1998) scores at 3 and 12 months

Overall study start date
01/01/2018

Completion date
01/05/2021

Reason abandoned (if study stopped)
Ethics approval not received.

Eligibility

Key inclusion criteria
1. Aged 35-70 years
2. Unilateral or bilateral trochanteric pain for greater than 3 months
3. Pain on walking and climbing slopes or stairs and/or lying on the affected side
4. Absence of groin pain
5. Tenderness on palpation of the greater trochanter
6. At least one of the following tests provocative of lateral hip pain: Combined hip flexion, abduction and external rotation (FABER); Active derotation test; Combined hip flexion, adduction and external rotation; Modified Ober test; 30 second single leg stance; Active hip abduction at end range adduction in side lying
7. Hip osteoarthritis excluded radiologically

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Evidence of osteoarthritis on X-ray (over grade 1)
2. Previous lower limb surgery affecting gait
3. Arthroplasty of the affected hip
4. Other neuromuscular or musculoskeletal conditions affecting gait or ability to exercise
5. Corticosteroid injections/physiotherapy/extracorporeal shock wave therapy (ECSWT) for GTPS in the last 3 months
6. Range of hip flexion <90 degrees
7. Significant lumbar pathology/pain
8. Previous lumbar nerve root entrapment or spinal surgery
9. Unable or unwilling to comply with study protocol
10. Unable or unwilling to offer written consent to the study
11. Unable to understand written or spoken English
12. Adverse reaction to steroid

Date of first enrolment
01/10/2018

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Royal Devon & Exeter NHS Foundation Trust

Sponsor details
Research and Development Unit. Noy Scott House. Royal Devon & Exeter NHS Foundation Trust.
Barrack Road.
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Other

Funder Name

Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication and dissemination of the results is planned for May 2021. This will include publication of an open access paper in a peer-reviewed journal and presentation at the Physiotherapy UK conference.

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date