

Does exercise help greater trochanter pain syndrome?

Submission date 18/06/2018	Recruitment status Stopped	☒ Prospectively registered ☐ Protocol
Registration date 25/07/2018	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 05/11/2019	Condition category Musculoskeletal Diseases	☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

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

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