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Greater trochanteric pain syndrome: a study comparing shockwave therapy to an ultrasound guided injection for the treatment of lateral hip pain

Submission date
26/11/2018

Recruitment status
No longer recruiting

Registration date
29/11/2018

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Greater Trochanteric Pain Syndrome (GTPS) is a term used to describe pain felt at the side of the hip. It is quite a common problem, affecting 10 – 25% of the population. You might be more likely to suffer from this condition if you have had a hip or knee replacement, or if you have a difference in leg length. Standard treatments for GTPS are usually physiotherapy, anti-inflammatory medication (painkillers), corticosteroid injections and very rarely surgery. Unfortunately, there isn't one treatment that appears to be better than another or that works for everyone. Currently, the standard treatment for GTPS involves an ultrasound-guided steroid injection to the painful hip. Steroids are powerful drugs which decrease inflammation and improve pain. Because it is given as a targeted injection, the effects of the steroid work in a specific area at high doses. Following the injection, patients are referred for physiotherapy. As there is no other treatment that can be offered following this, patients are usually discharged back to the care of their GP. Extracorporeal Shock Wave Therapy (ESWT) is a machine that delivers a high energy sound wave. When this sound wave is targeted over soft tissue like a tendon, for example, it increases the chemicals the body produces to ease pain and makes new blood vessels grow. ESWT has been found to be of benefit to some patients suffering with similar conditions such as Achilles Tendinitis, Plantar Fasciitis (Policeman's Heel) and Tennis Elbow. To date, there have only been a few studies to see if ESWT helps patients suffering with GTPS. However, the studies that have investigated ESWT treatment for GTPS found it reduced pain in the majority of patients. There are many studies that show injections have good effects and that is what is currently offered as treatment. The aim of this study is to compare this relatively new treatment (ESWT) to the standard treatment (corticosteroid injection).

Who can participate?
Patients aged over 18 with Greater Trochanteric Pain Syndrome (GTPS) who have not responded to treatment for their symptoms.

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 undergo three ESWT treatments by a fully trained member of the team, usually one per week. Each treatment lasts about 5 minutes. The treatment is targeted over the most tender spot identified by the participant. Some patients have described the treatment to be 'a little uncomfortable', and some patients have described the treatment to be 'painful'. If participants cannot tolerate the treatment it can be stopped straight away. Participants are given a diary and are asked to record any changes in their activity or pain levels or any concerns they have. Group 2 are treated with one guided injection into the painful area using an ultrasound machine performed by one of the consultant hip surgeons. The injection contains a local anaesthetic which might make the area feel numb and reduce pain in the short-term (hours) and a corticosteroid drug that might ease symptoms in the longer term. Participants are given a diary and asked to record any changes in activity or pain levels or any concerns they have.Both Groups 1 and 2 attend two formal physiotherapy sessions. They are assessed by a physiotherapist and taught specific GTPS exercises. About 2 weeks later their exercise technique is reviewed by the physiotherapist and any rehabilitation concerns are addressed. They are advised to continue GTPS exercises for a minimum of 3 months. About 3 months after the injection or ESWT participants are asked to complete questionnaires, their diary entries are reviewed and they are examined by one of the consultant hip surgeons. After 12 months participants are asked to complete some questionnaires and are examined by one of the consultant hip surgeons.

What are the possible benefits and risks of participating?
Either treatment might reduce pain. Furthermore, if participants still have symptoms and the study finds one treatment to be superior to the other, they will be offered this treatment. Participants might not gain any benefit from the treatment they receive and their pain/ symptoms may remain unchanged. The risks associated with ESWT are low, but might involve: increased pain in the treated area in the short term (during the treatment and subsequent week) or in the longer term, localised bruising, skin redness and or swelling, or tendon rupture. This is a very rare side-effect of shockwave therapy. If this were to occur, participants may undergo further investigations, for example an MRI scan. A decision would be made about further treatment on an individual basis. The risks associated with a corticosteroid injection are low, but might involve: increased pain in the treated area in the short term (during the treatment and subsequent week) or in the longer term, localised bruising, skin redness and or swelling, infection, or tendon rupture. This is a very rare side-effect of a steroid injection. If this were to occur, participants may undergo further investigations, for example an MRI scan. A decision would be made about further treatment on an individual basis.

Where is the study run from?
The Robert Jones and Agnes Jones Orthopaedic Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2014 to April 2018

Who is funding the study?
1. Impact Medical Ltd
2. The Orthopaedic Institute

Who is the main contact?
1. Dr Teresa Jones
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Additional identifiers

Protocol serial number

19219

Study information

Scientific Title
Does focused extracorporeal shockwave therapy improve greater trochanteric pain syndrome compared to an ultrasound guided steroid injection?

Study objectives
To discover whether focused extracorporeal shockwave therapy (ESWT) is a more effective treatment for Greater Trochaneric Pain Syndrome (GTPS) than the current standard treatment of a corticosteroid injection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - South Birmingham, 03/06/2015, ref: 15/WM/0170

Study design
Randomised; Interventional; Design type: Treatment, Other

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal Disorders, Primary sub-specialty: Non-pharmacological Interventions; Health Category: Musculoskeletal; Disease/Condition: Other soft tissue disorders

Interventions
128 patients were recruited to the study and randomised into two arms. Randomization was carried out using dedicated computer software (StratOs vs 1.34, Orthopaedic Institute Ltd, Oswestry, UK) and stratified by age, sex, and baseline visual analogue pain score and Harris Hip Score to achieve balanced groups with respect to these four variables.

Group 1 had three doses of ESWT followed by physiotherapy. Group 2 had a single ultrasound guided corticosteroid injection followed by physiotherapy.

Shockwave
Group 1 received a course of focused shockwave therapy by a fully trained member of the team (as per manufacturer’s guidelines). The patient was positioned in a lateral position and the most clinically tender area was identified on examination. Using the Piezowave 2 (Impact Medical Ltd, Liverpool, UK) a F10G6 transducer probe with a 50mm attachment was used to deliver 2500 shocks. The power level was set between 0.15 - 0.35mJ/mm2 depending on patient tolerance. This was repeated at weekly intervals for a total of three treatments.

Corticosteroid Injection
Group 2 underwent an ultrasound guided corticosteroid injection. This was administered in a clinic setting. All injections were performed by the same consultant hip surgeon (SCL). Under aseptic conditions, 80mg of depo-medrone (methylprednisolone) with 3.5ml 0.5% bupivicaine and 3.5ml 1% lignocaine were combined in a single syringe and injected using a long 21G (green) needle under ultrasound guidance to target bursae and tendon insertions whilst avoiding wholly intramuscular or intratendonous injections. Patients were monitored for 15 minutes following the procedure before being allowed to resume their normal activities

Physiotherapy
Directly following the treatment, both groups were seen by the same senior physiotherapist, assessed and given an exercise program comprising progressive slow repetitive exercises. Strengthening exercises included bridging, clam, hip abductor against gravity in side lying as well as specific stretching for hip flexors and gluteals. General advice was given on continuation of regular painkillers and cryotherapy, and avoidance of anti-inflammatory medication for a short period post-treatment. Continuation of usual activity was discussed but patients were encouraged to refrain from sporting activity for a short period post-treatment. Education was provided on expectations in symptoms post injection/shockwave therapy. Patients were reviewed two weeks after their initial assessment by the same physiotherapist and then reviewed on further occasions as felt appropriate by the physiotherapist, depending on clinical presentation and any difficulties with the programme up to a total of 6 sessions. All patients were assessed and followed up by the same physiotherapist to reduce bias. All patients had access to an online video of their exercise programme, as well as a paper copy given to them at the start of their treatment. Patients had access to a helpline where they could speak with their physiotherapist should any questions/problems arise.

Both groups were followed up at 3 and 12 months to assess pain, function and quality of life scores.

Intervention Type
Mixed

Primary outcome(s)
Pain measured using the visual analogue pain score (VAS) at baseline, 3 and 12 months post intervention

Key secondary outcome(s))
1. Function assessed using the Harris Hip Score (HHS) and Trendelenburg test at baseline, 3 and 12 months post intervention.
2. Quality of life assessed using the SF-36 at baseline, 3 and 12 months post intervention.
3. Symptom improvement assessed using a Likert scale at 3 and 12 months.
4. Completion of physiotherapy or any problems with any treatments received, assessed using a patient diary kept for 1 year and returned at final follow-up

Completion date
27/04/2018

Eligibility

Key inclusion criteria

A patient is eligible for the trial if the patient:
1. Is aged 18+ years
2. Has symptoms consistent with GTPS for at least 6 months
3. Failed conservative management in any other care setting
4. Patient is willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
104

Key exclusion criteria
A patient is ineligible for the trial if the patient:
1. Has hip joint osteoarthritis requiring treatment on a plain radiograph
2. Had surgical treatment specifically targeted at GTPS within last 6 months e.g. bursectomy/ITB lengthening
3. Has ipsilateral Total Hip Replacement. (patient will not be able to undergo corticosteroid injection in clinic setting)
4. Has contraindictions to ESWT treatment; pregnancy, anticoagulant therapy, advanced peripheral neuropathy, local infection, malignancy, unresolved fractures.
5. Has a previous history of complications with ESWT
6. Has a recent history of acute hip trauma
7. Has a recent history of acute sciatica
8. Is not able to attend or comply with treatment or follow-up scheduling
9. Participates in any other clinical trial

Date of first enrolment
28/07/2015

Date of final enrolment
18/04/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Robert Jones and Agnes Jones Orthopaedic Hospital NHS Foundation Trust
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Sponsor information

Organisation
The Orthopaedic Institute

ROR
https://ror.org/030mbcp39

Funder(s)

Funder type
Industry

Funder Name
Impact Medical Ltd

Funder Name
The Orthopaedic Institute; Grant Codes: 157

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms C Heaver (catriona.heaver@googlemail.com).

IPD sharing plan summary
Available on request

Study outputs

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Results article		17/11/2021	16/08/2022	Yes	No
Abstract results	results presented at the British Hip Society (BHS) Meeting	02/05/2019	24/01/2020	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 0.8	02/06/2015	16/08/2022	No	No