

Physiotherapy versus Cortisone Injection versus Wait and See for chronic LatErAl hiP pain: a randomized controlled trial (LEAP study)



THE UNIVERSITY OF
MELBOURNE

Centre for Health, Exercise and Sports Medicine
Physiotherapy, Melbourne School of Health Sciences
Phone (03) 8344 4171

Information Statement

We invite you to participate in our research project (called LEAP) which is being conducted at the University of Melbourne and would like to give you some background information on why we think this project is important and what is required if you decide to join us in this research.

What is the purpose of the study?

Lateral hip pain (pain at the side of the hip) is very common in the community and particularly in active women. Some studies state that 1 in 4 women over the age of 55 have this problem. The pain at the side of the hip can be very debilitating and often affects sleep, walking, going up stairs, prolonged sitting and getting up after sitting. The management of lateral hip pain is difficult and the pain can persist for months or even years. Previously this was diagnosed as bursitis, but recent research using ultrasound and MRI (magnetic resonance imaging) has shown the problem is usually due to degeneration (tendinopathy), and sometimes a tear in the tendons of the muscles at the side of the hip. The bursitis (a collection of fluid) appears to be secondary to the tendon injury. It is common that either a corticosteroid injection or an exercise-based physiotherapy program is prescribed for this condition, but there is no good research regarding which is better, or if in fact these treatments are any better than adopting a wait and see approach. It is not uncommon for patients to be given some information about their condition as well as being asked to adopt a wait and see approach for a period of several months to allow the condition to resolve spontaneously. The purpose of this study is to compare the effects of three possible approaches to treating long standing lateral hip pain: (a) a single cortisone injection, (b) an eight-week physiotherapy exercise program and (c) adopting a wait and see approach. The results will help us to determine the best treatment to manage this condition.

You are invited to participate in this research project, which is being conducted by Professor Bill Vicenzino, Professor Kim Bennell, Professor Paul Hodges, Dr Alison Grimaldi, Dr Rebecca Mellor, Dr Henry Wajswelner, Mr Tim Wrigley and Miss Philippa Nicolson.

Who can participate?

We require people who currently have lateral hip pain on most days for three months or more. You can participate in the study if you are aged 35-70 years; have lateral hip pain of musculo-skeletal origin (also called gluteal tendinopathy), have a good understanding of written and spoken English and are able to attend treatment sessions at the trial clinics consistently once to twice a week for the 8 week duration of the trial if you are allocated to the physiotherapy group. You are not eligible if you have had hip or knee surgery / joint replacement, are pregnant or breast-feeding, have had a cortisone injection in the side of the hip in the last 12 months, have had physical treatment or exercise therapy for your hip in the past three months, cannot do the exercises due to arthritis or other conditions, have groin, buttock or back pain worse than the hip pain, have a non musculoskeletal condition possibly causing your hip pain, if you have a needle phobia, a known allergy to corticosteroids or current use of aspirin or vaccines (due to their reaction with cortisone injections) or if your hip condition is the subject of a legal, Workcover or other third party claim. If you presently participate in high load sport you are not eligible to take part in this study. You also cannot participate if you have a pacemaker, metal implants, pregnancy or claustrophobia, as these would exclude you from being able to have an MRI scan.

What does the project involve?

To summarise, this project involves a physical screening assessment, baseline testing which will comprise clinical tests, a 3-D assessment of your walking as well as completion of a set of questionnaires, and a hip X-ray and hip MRI to determine whether you are eligible to participate. If you are ineligible at any of these stages we will provide you with a full explanation for your exclusion from the study. You will then be randomly allocated to one of 3 groups - a physiotherapy treatment group, a cortisone injection group or a wait and see group. Questionnaires will be sent to you by mail or email at 4, 12, 26 and 52 weeks after commencement of the program. You will also be required to return to the University of Melbourne for

reassessment of the clinical tests, walking and questionnaires at week 8. The study aspects are described in further detail below.

Physical screening:

First we need to determine whether you are eligible to be included in the study. To determine your eligibility, you will be asked to attend an appointment at the University of Melbourne, Department of Physiotherapy for physical screening, performed in privacy by an experienced physiotherapist. The screening assessment is similar to what a physiotherapist would normally perform in clinical practice if a client attended with chronic hip pain. Bring any hip X-rays/scans with reports that you may have. You will need to wear or bring suitable shorts to allow hip examination to see if you have the type of hip condition that is eligible for the study. The screening assessment will involve checking for pain and tenderness around the outside of your hip, and assessing your hip, back and knee motion. These tests will take approximately 20 minutes. Unfortunately, the physiotherapist will not be able to give you any advice or treatment during the assessment appointment. If you are deemed to be ineligible for the study, you are free to see your doctor, the physiotherapist or another health care professional of your choice for advice or treatment at your own cost and convenience thereafter.

Assessments:

If you are deemed suitable to take part, you will then immediately undergo the baseline assessment, which will take approximately 1.5 hours. It will involve completing a set of questionnaires which ask about your personal details, hip pain and function, your medications and usage of health practitioners and home support, physical activity levels and psychological factors related to having hip pain such as your confidence in being able to cope with the pain.

The physical tests performed will include measurement of your height, weight and waist circumference as well as the strength and flexibility of the muscles around your hip. We will also be assessing your walking and stair climbing patterns. Reflective skin markers and passive electrodes will be placed over your skin at various sites such as the ankle, knee and hip using adhesive tape. If need be, we will shave the sites with a single use disposable razor to remove excessive hair. The markers on your skin will be tracked as you walk along a walkway and as you step up and down several steps. From these tests, we will be able to analyse the movements at your hip, knee and ankle, as well as the forces acting across each joint and the activity of your muscles.

Imaging assessment:

Following clinical screening, you will be referred for an MRI scan of your hip at Victoria House Medical Imaging in Prahran. This is not an X-ray, there is no radiation exposure and it is a very safe imaging test. For the MRI, you will be asked to lie on a narrow table that can slide inside a large tunnel-like tube within a scanner. The scanner creates a magnetic field around you, then pulses radio waves at the knee.

You will also receive an X-ray of your pelvis and hip, at the same appointment. There is a low risk associated with having this X-ray examination, as you will be exposed to small amounts of radiation. Please advise the research team if you have had recent X-rays for any other reason, or if there is the possibility that you might be pregnant.

The imaging appointment will take approximately 1 hour.

If you have had a suitable standing x-ray of your hip within the previous 12 months, and have access to the images to show the researchers, you will not need to undergo that particular scan.

Follow-up:

The same questionnaires you completed at baseline will be sent to you by mail or email at four, 12, 26 and 52 weeks after commencement of the program. These can be completed at home and posted back to us via a reply-paid envelope, which we will provide or emailed back to us. After 8 weeks, you will also be required to return to the University of Melbourne, for reassessment of the clinical measures and completion of the questionnaires.

Interventions:

After screening and baseline assessment, you will be randomly assigned to one of three groups (1) physiotherapy group, (2) the cortisone injection group, or the (3) 'wait and see' group. You have a **33%** chance of being allocated to either group. You will be asked to avoid having any other treatment for your hip pain if possible during the study apart from taking any regular medication you may be using. All groups will be asked to keep a simple diary of any changes in symptoms, any changes in medications, or any new treatments over the course of the study.

For the injection group, you will go back to Victoria House Medical Imaging to have the injection given under ultrasound imaging control. You will be given advice on what to do and what to avoid after the injection. The injection will be performed by a qualified medical practitioner using aseptic procedures. Cortisone, which is a powerful anti-inflammatory medication, will be used for the injection. This will be placed into the tender area

of your hip, and 1ml of fluid will be injected into the fluid sac around the tendon. Cortisone is not a pain relieving medication: it only treats the inflammation, so when pain is decreased from cortisone it is because the inflammation is diminished. Cortisone injections usually work within a few days, and the effects can last up to several weeks. In addition, 2mls of Bupivacaine, which is a local anaesthetic, will also be injected at the same time.

For the physiotherapy group, you will be given an appointment to attend a session with one of the project physiotherapists at a trial clinic in Melbourne. The physiotherapists are located at various sites and you can choose the site that is most convenient for you. You will be asked to attend the physiotherapist on 10 occasions over 8 weeks. It will take one hour for the physiotherapist to show you your program at the initial appointment. All subsequent appointments will be 30 minutes in duration. The physiotherapist will assess you, show you your exercise program and make sure you can do the exercises safely, comfortably and correctly. You will be shown both clinic-based and home-based exercises. During this time you will be required to perform daily home exercises and will keep a simple diary of your exercise participation. The exercise programs will include floor exercises as well as exercises using specially designed exercise equipment. You will also be given advice on what to do and what to avoid.

For the 'Wait and See' group, you will attend one 30 minute session with one of the project physiotherapists at a trial clinic in Melbourne. The physiotherapist will discuss your condition with you and provide you with some information about your hip pain and its usual course. You will not be given any other specific treatment.

Are there any costs for me?

All treatments including the scans and injections and treatment sessions with the physiotherapists at the trial clinics are provided at no cost to yourself but all your travel, parking or other costs associated with attending the sessions is your own responsibility. We will provide you with free parking when you come in for testing at the University of Melbourne.

Are there any potential risks or side effects?

There is a risk that you may experience increased pain during examination and when asked to do some of the measurement tests. The risk is no more than that of visiting a physiotherapist or doctor for your hip pain, and having a normal examination and treatment. The risk will be minimised if you follow the instructions not to push into pain during the testing. Should you experience anything painful or distressing, you are asked to report this immediately to the researcher who will assess the situation and modify or cease the testing as appropriate.

MRI scanning involves lying still inside a tunnel and can affect people with claustrophobia. If you suffer from this condition you should notify the researchers. There is a side effect related to the use of MRI in individuals with metal in the body. Thus it is imperative that you inform the investigator of your full medical history and of surgical procedures and any metal implants. You must also let the researchers know if you may be pregnant. You will be given a safety screening form to complete to ensure that it is safe for you to be scanned by the MRI machine. If the practitioner who is assessing your MRI scan believes that you have an abnormal finding that is potentially significant, you will be notified and referred to an appropriate practitioner for further management and investigation.

This research study involves exposure to a very small amount of radiation. This is from the hip x-ray. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The effective dose from this study is about 0.54 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.

There are also risks and side effects associated with cortisone injection for your hip condition, the main one that has been identified in a 2012 systematic review is pain soon after the injection but this is short lived and should not last longer than several hours.

Cortisone injection generally for other tendon pains (e.g., Achilles, knee, elbow and shoulder studied in a comprehensive review in 2010) have a very small risk of the following side effects: (a) local reactions at the injection site, with swelling, tenderness, and warmth, or possible post-injection flare, or infection, or small areas of skin de-coloration, or wasting of small areas of tissue under your skin (will look like a local hollowing in the area of the injection). For Achilles tendon pain, there is a less than 0.1% chance of a tendon rupture, which was one case in 991 Achilles tendon patients injected with cortisone injection, but importantly it was deemed to be related to resuming a very rigorous sport (handball) two months after two injections without gradually building up and training for the sport. The study you are currently enrolling into will only use one injection and you will be given advice to gradually return to usual physical activity. These side effects occur infrequently when this injection is used for other tendons, but it has not been reported for the hip tendon pain that you have. If you experience any marked increase in pain after treatment, you should report this to the

researchers as soon as possible. To do this, please telephone Pippa Nicolson on 03 8344 0556. Treatment, if required, will be recommended and provided. Should you attend your local health care practitioner or hospital for any adverse event, please tell Prof Bennell at your earliest convenience, as it is important that adverse events are recorded.

During the exercise program, you may experience increased pain or injure yourself while you are performing the exercises. The pain may be felt afterwards or the next day, especially when you first commence the exercise program. To minimise this, you will be given clear instructions by the physiotherapist to gradually increase your exercises and do them within the limits of pain. The risk is minimised if you follow the instructions carefully and report any increase in symptoms or injury immediately to the therapist.

Some of the questionnaires you will be asked to complete involve you considering your pain and disability as well as your ability to cope. This may be upsetting for some people although we have not found this to be the case in our experience. It is important that you notify the researchers if you are uncomfortable in any way about the questions, and you may choose not to answer certain questions.

Are there any potential benefits?

By participating in the study you may find you gain some improvement in pain and in your ability to carry out normal activities. Importantly, you will also be helping us find out what to recommend to others experiencing lateral hip pain in the future.

How is this research funded and are there any disclosures?

This study is being funded by a program grant from the National Health and Medical Research Council. If you are member of staff or a student at the University of Queensland or University of Melbourne, your voluntary decision to take part or not will not affect your employment, results or any future dealing with the University. Dr Grimaldi is a private physiotherapy practitioner who owns a business specialising in treating clients with hip pain and educating physiotherapists in this area. However, she will not be involved in analysing the trial data.

What if I have any concerns during the study?

The Principal Investigators will be available throughout the study if you have any questions. This project has been approved by the Human Research Ethics Committee of the University of Queensland and University of Melbourne. If you have concerns about the way the study is being conducted you should contact the Executive Officer, Human Research Ethics, The University of Melbourne, +61 3 83442073

Can I withdraw from the study if I wish?

Your participation in this study is voluntary. If you do not wish to take part you are under no obligation to do so. Also, if you decide to take part but later change your mind, you are free to withdraw from the project at any stage. You may also withdraw any unprocessed data previously supplied by you. Your decision about whether or not to participate or to continue in the study will not affect your future medical care in any way.

Will my details be kept confidential?

The confidentiality of your participation is assured by our procedure, in which a code number and not your name will identify you. No findings that could identify you will be published and access to individual results is restricted to the investigators. Coded data will be stored for 15 years. All data and results will be handled as per the guidelines set out by the National Health and Medical Research Council. This project is subject to the requirements of the Human Research Ethics Committee of the University of Melbourne. However, you must be aware that there are legal limitations to data confidentiality.

How do I get more information?

You should ask for any information you want. If you would like more information about the study, or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the researchers. Before deciding whether or not to take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this.

How will I receive feedback?

A summary of the study findings can be sent to you if you wish. You will also be able to contact the research staff to receive verbal feedback during or after the study.

What to do if you want to participate in this study

If you are willing to participate, you should also read the attached informed consent form, which you will need to sign with us to indicate your willingness to take part in the study. If you do not yet have an appointment to begin, please call Pippa Nicolson on (03) 8344 0556 or email pnicolson@unimelb.edu.au and ask to make an appointment for eligibility screening and entry into the trial.

Thank-you for your interest in this research. This statement is yours to keep.

About the researchers:

Prof Bill Vicenzino (07 33652781) is the Chief Investigator and is the Head of the Division of Physiotherapy at The University of Queensland. He has conducted a number of clinical trials in various musculoskeletal conditions, and is particularly interested in the area of tendinopathy.

Prof Kim Bennell (03 83444135) is Director of the Centre for Health, Exercise and Sports Medicine, at the School of Health Sciences, University of Melbourne. Her research focuses on conservative non-drug management of musculoskeletal conditions including osteoarthritis and osteoporosis with an emphasis on the role of exercise in both prevention and management. She is the Co-ordinator of the Melbourne arm of the study.

Professor Paul Hodges (07 33655529) is an NHMRC Principal Research Fellow/Professorial Research Fellow at the University of Queensland. His research focuses on neuromotor control of movement and stability, and changes in this system with pain.

Dr Alison Grimaldi (07 33424284) is a PhD physiotherapist with special expertise in hip conditions. She is in Private Practice in Brisbane.

Dr Henry Wajswelner (0428292265) is an experienced Specialist Physiotherapist and is in charge of the Clinical Masters programs at Latrobe University.

Dr Rebecca Mellor (07 33651803) is a Senior Research Officer in the Department of Physiotherapy, The University of Queensland, and a PhD Physiotherapist with an interest in musculoskeletal conditions of the lower limb.

Mr Tim Wrigley (03 8344 4171) is the Director of the Movement Research Laboratories at the University of Melbourne, School of Health Sciences.

Ms Philippa Nicolson (03 8344 0556) is a research physiotherapist in the Centre for Health, Exercise and Sports Medicine, University of Melbourne.

To contact any of the researchers, please telephone them on the numbers supplied