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The HAPI 'Hip Arthroscopy Pre-habilitation Intervention' study

Submission date	Recruitment status	[_] Prospectively registered
16/10/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/11/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/01/2017	Surgery	

Plain English summary of protocol

Background and study aims
Hip arthroscopy is a keyhole technique used to gain access to the hip joint, and procedures can then be used to correct underlying femoro-acetabular impingement (a condition in which the bones of the hip are abnormally shaped, causing them to rub against each other and cause damage to the joint) and certain other abnormalities. This research study will investigate whether exercises before hip surgery (pre-habilitation) affect the outcome from hip arthroscopy for femoro-acetabular impingement. The information gained can then hopefully used to help future patients undergoing the same procedure.

Who can participate?
Men and women aged 18 years and over who have not had any previous hip surgery and have been diagnosed with femoro-acetabular impingement by their orthopaedic surgeon and are listed for a hip arthroscopy.

What does the study involve?
On your first visit to the clinic, eight weeks before surgery, you will be assessed for muscle weakness in your legs by a physiotherapist using a device called a dynamometer. This is a handheld device that you will be asked to push your leg against, this will measure the force of your movement. You will also be asked to complete two short questionnaires. You will be randomly allocated to one of two groups when you telephone to book your visit. One group will be taught to carry out certain exercises before surgery, the other will receive massage to the involved leg. The exercise group will be given 10 simple exercises to do once a day for the eight weeks before surgery, and a diary to record this.
The second visit will be one week before surgery where your muscle weakness will be re-measured and repeat questionnaires completed. Both groups will receive a colour booklet called The hip arthroscopy rehabilitation guide for patients and therapists .This is a step by step guide to post-operative hip arthroscopy rehabilitation which has been written and researched by the author following her many years of working in specialist hip physiotherapy. You will be taught exercises to do following surgery at this visit.
The third visit will be at two weeks following surgery where measurements will be retaken, gait (walking) will be checked and exercises taught as per the guide. Massage of the hip and leg muscles can be carried out if the patient wishes.

The fourth visit will be at six weeks following surgery where measurements will be retaken. A hydrotherapy session in the pool will be available to participants. The participant will also receive a colour booklet called Hydrotherapy exercises following hip arthroscopy surgery. Gait will be checked and exercises taught as per the guide.
The fifth visit will be at 12 weeks following surgery where measurements will be retaken and there will be two questionnaires to complete. A personal exercise program will be given to help you continue with your recovery. Patients can choose if they wish to receive massage or hydrotherapy at this visit.This package of physiotherapy will be instead of the NHS physiotherapy you would normally receive; you do not attend both. Therefore, the choice is that you decide whether to have the NHS physiotherapy care or the private care detailed above.

What are the possible benefits and risks of participating?
The benefits of participating in the study are that you are receiving private physiotherapy, massage and hydrotherapy in a hip specialist clinic free of charge. You will also benefit by being given detailed colour rehabilitation and hydrotherapy guides specifically written to help you in your recovery. The research centre has free parking, disabled access, a crèche and a café. It is hoped that the results of this study will help inform surgeons and physiotherapists on which areas to focus on to improve patient care and outcome following surgery. There are no known health risks associated with taking part in this study. The only known disadvantage would be that you would need to travel to Physiocure in Leeds, UK to take part.

Where is the study run from?
Physiocure Physiotherapy Clinic, Leeds, UK.

When is the study starting and how long is it expected to run for?
The study will be starting in October 2013 and will run until June 2014.

Who is funding the study?
Investigator initiated and funded, UK

Who is the main contact?
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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
001

Study information

Scientific Title
The HAPI 'Hip Arthroscopy Pre-habilitation Intervention' study. Does pre-habilitation affect outcomes in patients undergoing hip arthroscopy for femoro-acetabular impingement?

Acronym
HAPI

Study objectives
The study aims to provide more information on the subject of exercises before and after keyhole surgery of the hip for hip impingement. Hip arthroscopy (keyhole surgery) is a surgical technique used to gain access inside the hip joint. Procedures can then be carried out to remove boney areas that are causing pain and impingement. The surgeon may also repair damaged structures at the same time.

Hypothesis:
1.Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement improves the Non-Arthritic Hip Score (NAHS) post-operatively
2. Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement improves the EQ-5D-5L post-operatively
3. Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement improves muscle power post-operatively

Null Hypothesis
1. Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement does not improve the NAHS post-operatively.
2. Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement does not improve the EQ-5D-5L post-operatively.
3. Pre-operative rehabilitation before hip arthroscopy for femoro-acetabular impingement does not improve muscle power post-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service, North East REC Centre, 30/09/2013, ref: 13/YH/0226
Research & Development Department at Harrogate and District NHS Foundation Trust, 03/10 /2013, ref: R0071

Study design
Prospective randomised controlled comparative pilot study

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
Hip Arthroscopy

Interventions
Intervention group: exercises will be taught to you eight weeks prior to surgery, that will be done at home. You will be individually taught the specific techniques of the exercises, given an accompanying colour guide and a diary.

The control group will receive a session of massage eight weeks before surgery.

Each patient will be seen a total of five times during the study. Each session will last one hour.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. The Non-Arthritic Hip Score (NAHS), which gives a score regarding pain, symptoms, function and your general activity
2. The EQ-5D-5L Score, this gives a five-digit number which will reflect your opinions regarding your health and well being

Measured eight weeks before surgery, one week before surgery, two weeks after surgery, six weeks and twelve weeks following surgery.

Secondary outcome measures
Isometric muscle power, measured using a hand-held dynamometer, a device that gives a numerical reading when pushed against. This will give a measurement so we can see how much force you can push with in certain movements.

Measured eight weeks before surgery, one week before surgery, two weeks after surgery, six weeks and twelve weeks following surgery.

Overall study start date
07/01/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Male and female aged 18 years and over who have not had any previous hip surgery
2. The subjects will have already been diagnosed with femoro-acetabular impingement by their orthopaedic surgeon and listed for a hip arthroscopy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. People under the age of 18
2. Those who have had previous hip surgery on either hip, or a diagnosis of hip dysplasia, avascular necrosis, rheumatological disorders
3. Patients with grade 3 or 4 osteoarthritic changes reported on x-ray prior to surgery

Date of first enrolment
15/10/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Physiocure Physiotherapy Clinic
Cookridge Hall Health & Fitness,
Cookridge Lane
Leeds
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LS16 7NL

Sponsor information

Organisation
Middlesex University (UK)

Sponsor details
c/o Dr Elaine Atkins
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N19 5LW

Sponsor type
University/education

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

ROR
https://ror.org/01rv4p989

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
09/01/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/01/2017		Yes	No
HRA research summary			28/06/2023	No	No