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Arthroscopic surgery for hip impingement versus best conventional care

Submission date
20/02/2014

Recruitment status
No longer recruiting

Registration date
28/02/2014

Overall study status
Completed

Last Edited
02/03/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The hip joint has two bones that fit together like a ball in a socket. In some people these bones press against each other and can cause pain. The medical term for this is femororacetabular impingement (FAI for short). Parts of the hip called the 'labrum' and 'cartilage' cushion the hip joint and allow the smooth friction-free movement. FAI can injure both the labrum and cartilage and also cause pain. There is now good evidence to suggest a link between FAI and the development of premature osteoarthritis (wear and tear) of the hip, but we do not know who best to treat FAI. There has been a rapid increase in the use of keyhole surgery to treat this condition. This operation is called 'hip arthroscopy'. During hip arthroscopy the patient is put to sleep and the surgeon passes a small telescope and tools into the hip joint through small cuts in the skin. The tools are used to reshape bone around the hip to prevent further impingement. Many patients have already undergone surgery and had improvements in pain and hip function in the short to medium term. However, this research was not compared to conventional care and it is possible that they may have similar levels of improvement without an operation. An alternative treatment option for patients is a course of best conventional care (a structured programme of exercise-based care supervised by a physiotherapist - this has been called personalised hip therapy) aimed at improving the muscle strength and control around the hip joint. There are fewer risks associated with this type of treatment and it is less expensive. We therefore propose a study to find out which of these two treatments is most effective for treating patients with FAI up to 12 months after treatment.

Who can participate?
The study aims to recruit 302 patients with hip pain, aged 16 and above.

What does the study involve?
Patients are randomly allocated to either undergo arthroscopic surgery or receive usual care. Participants will receive their allocated treatment and will then be required to complete some questionnaires at 6, 12, 24 and 36 months. At 12 months we will conduct our first analysis to measure the effectiveness of the two treatments.

What are the possible benefits and risks of participating?
There are no specific benefits to the participating patients, but future patients should benefit as

the study will provide information on how best to treat this condition. The risks are small and include infection, bleeding, numbness, osteonecrosis (death of bone tissue) and neck fractures. For those patients allocated to usual care there is a small risk with pain medications and joint injections. However, the main risk is muscle soreness and temporary increases in pain from exercises.

Where is the study run from?
The study is run from 25 NHS Trusts throughout the UK.

When is the study starting and how long is it expected to run for?
It is expected that recruitment will start in July 2014 and participants will be enrolled onto the study over a 2-year period.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Damian Griffin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/103/02

Study information

Scientific Title
Full randomised controlled trial of Arthroscopic Surgery for Hip Impingement versus best CoNventional Care

Acronym
UK FASHIoN

Study objectives
What is the clinical and cost-effectiveness of hip arthroscopy for femororacetabular impingement (FAI) in comparison to best conventional care?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1310302
Protocol can be found at: http://www.nets.nihr.ac.uk/projects/hta/1310302

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, 01/05/2014, REC ref: 14/WM/0124

Study design
Multi-centre 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 contact Rachel Hobson (r.w.hobson@warwick.ac.uk) to request patient information sheet.

Health condition(s) or problem(s) studied
Femoroacetabular impingement (FAI)

Interventions
Participants will be recruited from 25 sites across the NHS in England, Scotland and Wales. Participation will be over a 3-year period. Participants will be allocated to either:
1. Hip Arthroscopic Surgery - performed by an experienced trained surgeon

2. Best Conservative Care - a package of physiotherapy-led therapy entitled 'Personalised Hip Therapy' given over a 12-week period with an option of two further booster sessions up to 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical effectiveness of hip arthroscopy, assessed by patient-reported hip-specific quality of life after one year

Secondary outcome measures
1. General health status and health-related quality of life after 12 months
2. Pattern of clinical change over 12 months
3. Patient satisfaction with treatment and outcome after one year
4. Number and severity of adverse events after treatment
5. Need for further procedures up to three years
6. Cost-effectiveness within the trial and for a patient's lifetime
7. Develop and report processes to optimise recruitment in an RCT or surgery versus non-operative care
8. Fidelity of delivery of interventions

Overall study start date
01/04/2014

Completion date
30/07/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 15/03/2016:
1. Age ≥16 (no upper age limit)
2. Symptoms of hip pain - patients may also have symptoms of clicking, catching or giving way
3. Radiographic evidence of pincer- and/or cam-type FAI morphology on plain radiographs and cross-sectional imaging, defined as:
3.1. Cam morphology - an alpha angle >55º;
3.2. Pincer morphology - a lateral centre edge angle of >40 degrees or a crossover sign on the anteroposterior radiograph of the pelvis
4. The treating surgeon believes the patient would benefit from arthroscopic FAI surgery
5. The patient is able to give written informed consent and to participate fully in the interventions and follow-up procedures

Original inclusion criteria:
1. Age ≥16 (no upper age limit)
2. Symptoms of hip pain - patients may also have symptoms of clicking, catching or giving way
3. Radiographic evidence of pincer- or cam-type FAI on plain radiographs confirmed with cross-sectional imaging, defined as alpha angle >55° or lateral centre edge angle >40°
4. The treating surgeon believes the patient would benefit from arthroscopic FAI surgery
5. The patient is able to give written informed consent and to participate fully in the interventions and follow-up procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
344

Total final enrolment
348

Key exclusion criteria
1. Evidence of pre-existing osteoarthritis, defined as Tonnis grade >1, or more than 2 mm loss of superior joint space width on AP pelvic radiograph
2. Previous significant hip pathology such as Perthes' disease, slipped upper femoral epiphysis, or avascular necrosis
3. Previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture
4. Previous shape changing surgery (open or arthroscopic) in the hip being considered for treatment

Date of first enrolment
01/07/2014

Date of final enrolment
30/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Clinical Trials Unit, Division of Health Sciences
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/08/2016		Yes	No
Results article	results	02/06/2018		Yes	No
Results article	results in Health Technology Assessment	01/02/2022	02/03/2022	Yes	No
HRA research summary			28/06/2023	No	No