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Feasibility study of a trial of arthroscopic surgery for hip impingement compared with non-operative care

Submission date 20/02/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/02/2012	**Overall study status** Completed	
Last Edited 16/09/2016	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/41/02

Study information

Scientific Title
UK FASHIoN: Feasibility study of a trial of Arthroscopic Surgery for Hip Impingement compared with Non-operative care

Acronym
UK FASHIoN

Study objectives
We plan to establish whether it is feasible to undertake an RCT of hip arthroscopy versus best conservative care for femoroacetabular impingement (FAI).

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/104102
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/55408/PRO-10-41-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES West Midlands, 15/02/2012, ref: 11/WM/0389

Study design
Feasibility study with a mulitcentre pilot 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 a patient information sheet

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

Interventions
Hip Arthroscopic Surgery - performed by an experienced trained surgeon.

Non-operative care - this will comprise a package of best conservative care; treatment options, including interventions that target patients pain (anti-inflammatory medication, hip joint

corticosteroid injection, postural adaptations, exercise, acupuncture, manual therapy techniques) and functional difficulties (lifestyle advice, gait modification, exercise and physical activity). The focus of this intervention will be an individualised, supervised and progressed exercise rehabilitation programme.

Secondary sponsor:
University of Warwick
c/o Dr Peter Hedges (Director of Research Support Services)

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Non-Arthritic Hip Score (NAHS)

Secondary outcome measures
1. IHOT-33
2. SF-36
3. EQ-5D

Overall study start date
01/03/2012

Completion date
01/09/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 04/02/2013:
1. ≥ 16 years of age
2. They have symptoms of hip pain - they may also have symptoms of clicking, catching or giving way
3. They show radiographic evidence of pincer- or cam-type FAI on plain radiographs and cross-sectional imaging
4. The treating surgeon believes that they would benefit from arthroscopic FAI surgery
5. Able to give written informed consent
6. Able to participate fully in the interventions

Previous inclusion criteria until 04/02/2013:
1. Aged 18-50
2. They have symptoms of hip pain - they may also have symptoms of clicking, catching or giving way
3. They show radiographic evidence of pincer- or cam-type FAI on plain radiographs and cross-sectional imaging
4. The treating surgeon believes that they would benefit from arthroscopic FAI surgery
5. Able to give written informed consent
6. Able to participate fully in the interventions

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. They have previous significant hip pathology such as Perthes disease, slipped upper femoral epiphysis or avascular necrosis
2. They have had a previous hip injury such as acetabular fracture, hip dislocation or femoral neck fracture
3. They already have osteoarthritis, defined as Tonnis grade >150, or more than 2mm loss of superior joint space width on AP pelvic radiograph
4. There is evidence that the patient would be unable to participate fully in the interventions, adhere to trial procedures or to complete questionnaires, such as cognitive impairment or intravenous drug abuse

Date of first enrolment
01/03/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Warwick
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry & Warwickshire (UK)

Sponsor details
c/o Mrs Ceri Jones (Research & Development Manager)
University Hospital, Coventry
Clifford Bridge Road
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England
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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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Results article	results	01/10/2016		Yes	No