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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof Damian Griffin

#### Contact details

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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:

- $1. \ge 16$  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
Coventry
England
United Kingdom
CV2 2DX

#### 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              |