

A magnetic resonance and histological investigation of articular cartilage damage in early stage degenerative disease of the hip joint and evaluation of synthetic labro-chondral graft implantation

Submission date 22/08/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 22/08/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 29/05/2020	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

14799

Study information

Scientific Title

A magnetic resonance and histological investigation of articular cartilage damage in early stage degenerative disease of the hip joint and evaluation of synthetic labro-chondral graft implantation (INTCLAPH)

Acronym

INTCLAPH

Study objectives

Healthy joints depend upon specialised cartilage (hyaline cartilage) that covers the surfaces of the articulating bones.

In the hip joint, the ball at the top of the thigh bone (femoral head) moves against a recess in the pelvis (the acetabulum). The acetabulum is deepened by the presence of a fibrous rim (the labrum) that helps to stabilise the joint and keep lubricating fluid between the rubbing surfaces.

When joints are damaged, the hyaline cartilage is lost and the joint becomes painful. In the hip, damage can be caused by repetitive injury to the labrum because the shapes of the ball and socket do not quite match. In time, the labrum begins to separate from the bony acetabular rim and the adjacent hyaline cartilage becomes unstable. As the damage progresses, the cartilage begins to peel away from the underlying bone, the femoral head then rubs against the damaged area and arthritis ensues.

Over the last few years, techniques have been developed, using keyhole surgery, that allow us to repair damage to the labrum and reshape the femoral head to avoid further injury. A number of strategies have also been developed to promote cartilage regeneration in areas of hyaline cartilage loss. These range from simply removing the damaged cartilage, making holes in the underlying bone (microfracturing) to the application of synthetic collagen graft patches. To date no one has compared these different strategies to find out which is the most effective. We propose to undertake a two-centre, prospective, randomised study, on patients with acetabular cartilage loss (adjacent to labral damage) and compare the four most commonly used repair strategies in order to find out which works best. Clinical outcome, X-rays, Computerised tomography (CT), Magnetic Resonance (MR) and biomarkers (blood and urine tests) will be used to evaluate the study subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/LO/0753

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Non-inflammatory Joint Disorders

Interventions

tbc, tbc

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

tbc; Timepoint(s): tbc

Key secondary outcome(s)

Not provided at time of registration

Completion date

15/01/2015

Eligibility

Key inclusion criteria

1. History of hip pain.
 2. Tönnis grade 0 or 1 radiographic changes.
 3. Hip Joint Space Width (JSW) > 2 mm.
 4. Arthroscopic confirmation of:
 - 4.1. Labro-chondral split
 - 4.2. Chondral defect grade 3 and 4 (Outerbridge, ICRS & UCL Classifications)
 - 4.3. Chondral defect size range 0.5 4.0 cm².
 5. Ability to provide informed written consent.
- Target Gender: Male & Female; Upper Age Limit 55 years ; Lower Age Limit 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. OA Grade > 1 (Tönnis scale)
2. Inflammatory joint disease
3. Previous dislocation or fracture of the affected hip
4. Previous non-arthroscopic surgery to the affected hip
5. History of back pain
6. Age <18 years and > 55 years
7. BMI > 30
8. Hip joint space = 2 mm
9. Previous hip joint sepsis or osteomyelitis
10. Metabolic bone disease
11. Osteoporosis
12. Avascular necrosis
13. Associated neurological disease
14. Diabetes
15. Pregnancy
16. Chronic use of narcotics or oral steroids
17. Heavy alcohol intake on a regular basis
18. Inability to give consent or cooperate with the study protocol
19. Non-English speaking patients
20. Patients who move outside United Kingdom

Date of first enrolment

15/08/2013

Date of final enrolment

15/01/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Epsom and St Helier University Hospitals NHS Trust

Carshalton

United Kingdom

SM5 1AA

Sponsor information

Organisation

St George's University of London (UK)

ROR

<https://ror.org/040f08y74>

Funder(s)

Funder type

Charity

Funder Name

Orthopaedic Research UK; Grant Codes: 491

Alternative Name(s)

The Orthopaedic Research UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No