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

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
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

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
tbc; Timepoint(s): tbc

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/08/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 45; UK Sample Size: 45

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

England

United Kingdom

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)

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Sponsor type
University/education

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
Orthopaedic Research UK; Grant Codes: 491

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

For-profit companies (industry)

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?
HRA research summary			28/06/2023	No	No