ISRCTN48911177 https://doi.org/10.1186/ISRCTN48911177

Autologous chondrocyte transplantation /implantation versus existing treatments

Submission date
18/05/2001

Recruitment status
No longer recruiting

Registration date
18/05/2001

Overall study status
Completed

Last Edited
16/03/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Defects in the cartilage covering the bones of the knee (chondral defects) do not heal by themselves. A technique to treat cartilage defects called autologous chondrocyte implantation (ACI) was developed in Sweden and has been used on many patients in the UK and US. The ACI treatment involves two operations. At the first operation a small sample of healthy cartilage is taken from the knee to a laboratory for the cells to be grown for 3-5 weeks, and at the second operation the cells are injected into the knee defect. This treatment appears to have been successful in treating many patients but has not yet been tested in a formal study. The aim of this study is to compare ACI with conventional treatments for patients who have had a failed primary treatment for chondral defects in the knee.

Who can participate?
Patients who are still getting symptoms from the defect in their knee cartilage despite having surgical treatment for it in the past.

What does the study involve?
Participants receive a full knee assessment and complete questionnaires about their knee function and how it affects their quality of life. Participants are randomly allocated into one of two groups. One group has the ACI treatment and the other group receive the most appropriate alternative treatment agreed with their surgeon. Both groups receive the standard physiotherapy and rehabilitation programme that is best for the treatment they received, and attend a follow-up appointment 2 or 3 months after surgery and again at 6 months and at 1 year after surgery. On each occasion participants complete questionnaires and their knee function is assessed. Because we want to compare the long-term outcome of the treatments participants are asked to return to the clinic 3, 5 and 10 years later. We also contact participants by post, phone or e-mail on one occasion each year for 10 years so we can check on their progress.

What are the possible benefits and risks of participating?
We hope that whichever treatment participants have will help them. However, this cannot be guaranteed. The information we get from this study may help us to recommend the best course

of action for patients in the future. For participants treated with ACI, in addition to the normal risks of knee surgery there is a small risk that they may experience an allergic reaction to a substance used in the cell transplantation. However, this reaction is very rare.

Where is the study run from?
The Robert Jones and Agnes Hunt Orthopaedic and District Hospital, NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2004 to December 2021

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof James Richardson
james.richardson@nhs.net

Study website
http://www.active-trial.org.uk/

Contact information

Type(s)
Scientific

Contact name
Prof James Richardson

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0200055

Study information

Scientific Title
Autologous Chondrocyte Transplantation/Implantation Versus Existing treatments: a randomised controlled trial

Acronym
ACTIVE

Study objectives
To compare autologous chondrocyte implantation with 'conventional' treatments for patients who have had a failed primary treatment for chondral defect(s) in the knee.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands, July 2004, ref:04/Q2604/10

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information leaflet in http://www.active-trial.org.uk/ACTIVESite/PILv3.1.doc

Health condition(s) or problem(s) studied
Orthopaedics

Interventions
Arm 1: Autologous chondrocyte implantation (ACI)
Arm 2: One 'conventional' treatment chosen by surgeon/ patient from following list: Debridement; Abrasion; Drilling; Microfracture; Mosaicplasty.

Arm 1 (ACI) is further randomised to receive a patch made from either:
a) Periosteum or
b) Collagen membrane

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to cessation of benefit: as defined when 2/3 assessment criteria show no improvement compared to preoperative assessment levels at least 12 months after surgery:
1. Independently assessed Lysholm Knee score
2. Patient self-assessed Lysholm Knee questionnaire
3. Independent assessor's judgement based on impact on quality of life, physical examination and functional observation

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/12/2004

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/11/2012:
1. Symptomatic chondral defect(s) on the medical or lateral femoral condyle, trochlea or patella suitable for either ACT or one of the existing conventional treatments (debridement, abrasion, drilling, microfracture, mosaicplasty)
2. Surgical treatment for the same defect carried out at least 12 months previously, that has not relieved symptoms
3. Not more than two defects, not kissing and total area not greater than 12cm2
4. Likely to comply with appropriate physiotherapy

Previous inclusion criteria until 09/11/2012:
1. Symptomatic chondral defect(s) on the medical or lateral femoral condyle or trochlea suitable for either ACT or one of the existing conventional treatments (debridement, abrasion, drilling, microfracture, mosaicplasty)
2. Surgical treatment for the same defect carried out at least 12 months previously, that has not relieved symptoms
3. Not more than two defects, not kissing and total area not greater than 12cm2
4. Likely to comply with appropriate physiotherapy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
1. Concurrent meniscectomy/osteotomy or untreated malalignment of patella
2. Generalised osteoarthritis, inflammatory condition or history of mesenchymal tumors
3. Patient in different clinical trial involving the knee, currently or in last 6 months

Date of first enrolment
22/12/2004

Date of final enrolment
09/11/2012

Locations

Countries of recruitment
England

Norway

United Kingdom

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic and District Hospital, NHS Trust
Oswestry
United Kingdom
SY10 7AG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
-
Keele
England
United Kingdom
ST5 5BG

Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR

https://ror.org/00340yn33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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