

# ACTIVE Trial Summary

(Autologous Chondrocyte Transplantation / Implantation Versus Existing Treatments)

**QUESTION:** Does Autologous Chondrocyte Transplantation / Implantation (ACI) offer longer-term benefits than standard procedures for the repair of isolated chondral defect(s) of the knee that remain symptomatic following previous treatment?

- ACTIVE is a prospective randomized trial comparing ACI with standard treatments for patients who have had a failed primary existing treatment for chondral defects of the knee.
- Existing treatment includes debridement, abrasion, drilling, microfracture, or mosaicplasty.
- The autologous chondrocyte suspension is retained by a membrane, which may be either periosteum or a porcine-origin collagen membrane, sutured to the edges of the defect and sealed with fibrin.

Patients that are randomized to the ACI arm are further randomized into either a collagen membrane or periosteal patch.

- The primary outcome measure is cessation of benefit of treatment.
- ACTIVE is funded by the Medical Research Council (MRC).

## Eligibility:

- Symptomatic chondral defect(s) on the medial or lateral femoral condyle or trochlea suitable for either ACI or one of the existing treatments; with no “definite” indications for, or “definite” contraindications against ACI.
- Not more than 2 defects, not kissing and total area not greater than 12cm<sup>2</sup>. Patients with 2 defects in the same compartment may be included if the defects are to be treated in the same way.
- Surgical treatment for the same defect, carried out at least 6 months previously, that has not relieved symptoms.
- No concurrent meniscectomy / osteotomy or untreated malalignment of the patella.
- No generalized OA, inflammatory condition or history of mesenchymal tumours.
- Likely to comply with appropriate rehabilitation and ongoing assessment.

- HIV, Hep B and C negative.
- Not in other clinical trial involving the knee currently or in last 6 months.

### Exclusions:

- ◆ Patients with osteochondral defects, defined as bone exceeding 3mm depth are excluded from the trial as are patients with a chondral defect exposing bone on the tibia.
- ◆ Ineligible if bilateral defects.

### Post-Op:

Following abrasion, drilling, microfracture or mosaicplasty, immediate post operative CPM and restricted weight bearing to protect regenerating tissue is recommended. After ACI, 6 hours post operative rest allows cell adherence. This is followed by CPM for 3 days and restricted weight bearing with crutches for up to 4 weeks. Progressive physiotherapy rehabilitation continues for at least 3 months for both patient groups.

### Assessments:

Functional Knee scores, QOL indicators and resource usage data is collected pre-operatively. This data collection is then repeated at 2-3 months, 6 months, 1, 3, 5, and 10 years in clinic.

In the intervening years, patients will be assessed annually by postal questionnaire.

Functional knee scoring employs Lysholm, IKDC, and Cincinnati Sports Activity Rating. The EuroQOL EQ-5D assessment tool is used to measure quality of life.

Data will be collected by a suitable person (senior physiotherapist) trained centrally in outcome assessment. The assessor remains blinded and is not involved in the usual clinical care of the patient.

### Further Information:

Mr M McNicholas, Consultant Orthopaedic Surgeon, Warrington Hospital, Lovely Lane, Warrington, Cheshire WA5 1QG. Tel: 01925 662919

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