# Intraarticular changes related to regenerative interventions for focal cartilage lesions

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Primary objective: Evaluate intraarticular environmental changes related to treatment for focal cartilage lesions in order to increase insight into the chain of events occurring during cartilage regeneration.Secondary Objective(s): Determine the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Tendon, ligament and cartilage disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON31699

**Source**
ToetsingOnline

**Brief title**
dGEMRIC, synovial fluid and cartilage regeneration

### Condition

- Tendon, ligament and cartilage disorders

**Synonym**
Cartilage lesions, focal cartilage degeneration

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cartilage regeneration, dGEMRIC, Homeostasis, Synovial fluid

## Outcome measures

### Primary outcome

Primary endpoint of the study will be 12 months after the surgical procedure.

At this time point we will evaluate the changes in dGEMRIC values, synovial fluid protein spectrum and clinical questionnaires (KOOS, VAS) at the several predefined time points. We will also compare the changes in dGEMRIC value and synovial fluid proteins to the clinical questionnaires.

### Secondary outcome

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# Study description

### Background summary

Articular cartilage trauma and degenerative cartilage disease as occurring during osteoarthritis (OA) are likely to be two opposite ends of a continuum, where a disturbance in joint homeostasis, caused by the presence of a cartilage defect, ultimately leads to a spiral of catabolic cues and generalized cartilage degradation. It has been suggested that environmental factors surrounding the cartilage defect causes discrepancy between the results of regenerative preclinical therapeutic cartilage research and that in clinical practice. Evaluation of the cartilage biochemistry, using highly sophisticated MRI techniques, and changes in catabolic and anabolic synovial fluid proteins before and after regenerative cartilage approaches increases insight in cartilage regeneration and might identify possible targets for future regenerative therapies or pretherapeutic interventions.

### Study objective

Primary objective: Evaluate intraarticular environmental changes related to treatment for focal cartilage lesions in order to increase insight into the chain of events occurring during cartilage regeneration.

Secondary Objective(s): Determine the potential of dGEMRIC as a follow-up tool for cartilage regeneration by monitoring the changes in T1GD values and correlating them to clinical questionnaires (KOOS, VAS) and identify changes in the synovial protein spectrum as related to treatment of focal cartilage lesions in order to possibly identify prognostic factors or targets for future therapies.

### Study design

All patients included in this study will receive the regular preoperative, perioperative and postoperative treatment and survey. They will receive an MRI scan (with dGEMRIC settings) as well as synovial fluid aspiration (to perform protein array analysis) from the affected knee within 1 month before surgery and at 3, 9 and 12 months follow-up. At these 4 time points patients will also be asked to fill out 2 questionnaires (KOOS and VAS). Except for the MRI (at preoperative, 9 and 12 months after surgery) these interventions are additional to the standard treatment follow-up.
The dGEMRIC T1 relaxation times will be calculated for the regions of interest (surgical site), the changes in protein spectrum over time will be analyzed and the clinical scores (resulting from the questionnaires) will be analyzed.

### Study burden and risks

Patients participating in this study, will undergo 4 MRI scans of their knee with special dGEMRIC settings. Each scan will take about 30 minutes to perform. Synovial fluid will also be aspirated from the affected knee before each MRI scan is obtained. Next to this patients will also be asked to fill out several questionnaires (KOOS and VAS) which will take around 15 minutes. Complications for both MRI and synovial fluid aspiration seldom occur.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients over 18 years of age
Diagnosed focal cartilage lesions
Submitted to either ACI or microfracturing

## Exclusion criteria

Contra-indications for gadolinium MRI scanning
Patients with inflammatory rheumatic disease
Patients with (a history of) kidney disease

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |

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| Start date (anticipated): | 26-06-2008 |
| Enrollment: | 42 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 13-05-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL21110.041.08 |