

Trial Description

Title

Correlation of clinical outcome with intraarticular cytokine concentrations following cartilage regeneration in knee and upper ankle joint

Trial Acronym

CORRCYT

URL of the trial

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Brief Summary in Lay Language

Lavage fluids of patients with cartilage lesions or suffering from osteochondrosis dissecans are prospectively collected during an arthroscopy performed for treatment. Patients without cartilage lesions serve as a control group, cartilage defects are treated by microfracturing by Autologous Chondrocyte Implantation, or drilling (ACI). Total protein content and concentrations of Aggrecan, bFGF, IGF-I, BMP-2, BMP-7, and IL-1beta are determined. Clinical status is evaluated using the validated scores (Lysholm, ICRS, AOFAS).

Brief Summary in Scientific Language

Lavage fluids of patients with cartilage lesions or suffering from osteochondrosis dissecans are prospectively collected during an arthroscopy performed for treatment. Patients without cartilage lesions serve as a control group, cartilage defects are treated by microfracturing by Autologous Chondrocyte Implantation, or drilling (ACI). Total protein content and concentrations of Aggrecan, bFGF, IGF-I, BMP-2, BMP-7, and IL-1beta are determined. Clinical status is evaluated using the validated scores (Lysholm, ICRS, AOFAS).

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000365**
- Date of Registration in DRKS: **2010/03/08**
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Date of Registration in DRKS: **2010/03/08**

Date of Registration in Partner Registry or other Primary Registry: **2009/01/12**

- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **335/08** , **Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1114-0910**
- Partner Registry-ID: **UKF001822 (Register Klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **M93.2 - Osteochondritis dissecans**
- ICD10: **M94.26 - [generalization M94.2: Chondromalacia]**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Lysholm Score, IKDC Score: validated scores about knee function

Secondary Outcome

Noyes Score, the Medical Outcomes Study Short Form-36 (SF-36), and visual analog scales (VAS) for knee pain strength and frequency: parameter for life quality

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/08/30**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

performance of an arthroscopy of the knee joint or the upper ankle joint, patients in the control group have no cartilage lesion in MRI and diagnostic arthroscopy, patients undergoing microfracturing or ACI have full thickness cartilage lesions graded III and IV according to ICRS classification of various size, agreement to participate in the study, age >18 years and <65 years

Exclusion criteria

alcohol or drug abuse, mental retardation with incapability to complete the necessary self-reports, joint effusion >30ml, persistent knee oder upper ankle joint instability, infection

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

DRKS-ID: **DRKS00000365**

Date of Registration in DRKS: **2010/03/08**

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■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

AO Deutschland

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URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.