PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Optimization of prosthesis planning using a digital X-ray system (EOS)

Trial Acronym

HipEOS

URL of the trial

[---]*

Brief Summary in Lay Language

**Goal of this study is to compare the preoperative planning with the hipEOS software and EOS images to preoperative planning based on conventional digital X-ray images. For EOS the patient is standing, for X-ray the patient is lying.
EOS is a new radiographic imaging system able to make full body X-ray images, simultaneously frontal and lateral from a standing patient. A further benefit of the EOS system is the low radiation dose.**

**We also want to study whether there is a relation between the static situation measured by EOS (leg length difference, leg deformation in the frontal plane) and the dynamics of gait e.g. joint loads in the knee and hip both preoperative and postoperative.
A gait analysis can measure functional gait in 3 dimensions by means of light reflecting markers on the skin and a force platform in the ground.**

A further goal of this study is to measure the concentration of COMP (cartilage oligomeric matrix protein) in the blood and correlate this concentration to the degree of osteoarthritis. Also the changes after the hip prosthesis has been put in will be documented as well as the relation to the joint loads during gait.

For this study 60 patients with hip osteoarthritis, age between 30 and 80 years, will be randomly divided in a digital radiograph planned group and an EOS planned group. Grouping will not have any effect on the planning surgery and care in our hospital as both methods are part of our clinical routine.

Brief Summary in Scientific Language

**Normally the planning is performed on preoperative anteroposterior (AP) pelvic digital radiographs. The radiograph is made with the patient in a supine position. An important error is the magnification effect which can lead to differences between the actual anatomy and the planned components. The fact that the radiograph is made with the patient in the supine position can have an effect on the postoperative position and the functional outcome.
With the EOS® system, a new radiographic imaging modality (EOS Imaging, Paris,**

France), full body X-ray images, simultaneously frontal and lateral, can be made from a standing patient. A 3D reconstruction of the hip, pelvis and lower limb can be used for the preoperative planning of the (cemented and cementless) total hip arthroplasty.
We expect that preoperative planning with the hipEOS software and EOS images is better compared to preoperative planning based on conventional digital radiography. This means the predicted components sizes are closer to the actual implanted sizes.

Functional gait parameters, like knee flexion can be measured by an instrumented gait analysis. A research question is to study the relation between the static situation measured by EOS® and the dynamics of gait. We expect that persons with a larger leg length discrepancy, leg misalignment in the frontal plane (genu varum/genu valgum) or rotational deformities show higher joint loads. A gait analysis can measure functional gait in 3 dimensions by means of light reflecting markers on the skin and a force platform in the ground.

A further goal of this study is to measure the concentration of COMP (cartilage oligomeric matrix protein) in the blood and correlate this concentration to the degree of osteoarthritis as well as to the gait parameter. With this setup it can be studied whether the hip arthroplasty improves the gait function and if the serum concentration of COMP returns to normal values.

For this study 60 patients with hip osteoarthritis, age between 30 and 80 years, will be randomly divided in a digital radiograph planned group and an EOS planned group by means of block randomization. Grouping will not have any effect on the planning surgery and care in our hospital as both methods are part of our clinical routine.

Organizational Data

- DRKS-ID: **DRKS00015053**
- Date of Registration in DRKS: **2018/08/01**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **497/15 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs

Health condition or Problem studied

- ICD10: **M16.9 - Coxarthrosis, unspecified**

Interventions/Observational Groups

- Arm 1: **Patients diagnosed to have a cementless hip arthroplasty will have a 3D gait analysis preoperative and one year postoperative. For the planning of the prosthesis these patients will have an EOS image (routine). Bloodsamples (5ml) will be taken preoperative (routine), 7 days (± 5 days) postoperatively (routine) as well as 3 months (± 4weeks) and 1 year (± 4weeks) postoperatively**
- Arm 2: **Patients diagnosed to have a cementless hip arthroplasty will have a 3D gait analysis preoperative and one year postoperative. For the planning of the prosthesis these patients will have an classis digital radiograph (routine). Bloodsamples (5ml) will be taken preoperative (routine), 7 days (± 5 days) postoperatively (routine) as well as 3 months (± 4weeks) and 1 year (± 4weeks) postoperatively**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The prosthetic sizes (cup and stem size) predicted with the TraumaCad® software in the one group and with the hipEOS software for the other group will be compared to the actual implanted sizes.

Secondary Outcome

1. The correlations between the static situation, defined by leg length discrepancy, degree of leg misalignment and degree of rotational deformity (calculated by SterEOS® on the postoperative EOS image), and the dynamics of gait (defined by joint loads, spatial-temporal parameters and range of motion).
2. COMP concentration from the blood samples.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Orthopedic University Hospital Friedrichsheim gGmbH, Frankfurt a.M.**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/05/13**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Patients diagnosed to have a cementless hip arthroplasty, free walking and standing without support.

Exclusion criteria

• BMI ≥ 30
• previous endoprosthetic interventions (ipsilateral and contralateral hip, knee and ankle joints)
• Surgical interventions on the musculoskeletal system during the previous 6 months.
• ASA-Klassifikation > 2
• progressive joint inflammation or destructive rheumatoid arthritis
• Neurologic diseases (z.B. Morbus Parkinson, stroke with paralysis, Muscular dystrophy, Epilepsy, Multiple Sclerosis, Paraneoplastic Neurologic Syndrom (PNS), Tremor, Alzheimer's disease, Huntington's chorea, Polio, cerebral palsy)
• injuries of the lower extremities
• no informed consent
• Patients with x-ray images which can be used for planning.

Addresses

- **Primary Sponsor**

  Orthopädische Universitätsklinik Friedrichsheim gGmbH

Primary Sponsor

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum der Studie mit dem Titel: "Optimierung der Prothesenplanung mittels EOS"**
- trial protocol (mandatory for transfer to Studybox) **Prüfplan (inklusive Amendment) der Studie mit dem Titel: "Optimierung der Prothesenplanung mittels EOS"**
- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum (Amendment) der Studie mit dem Titel: "Optimierung der Prothesenplanung mittels EOS"**

** 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.*