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

Trial Description

Title

Prospective randomized multicenter clinical observationan of a novel cement spacer implants for for knee implant-two stage exchange after septic implant loosening

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Evaluation of novel cement spacer implants for the two-stage total knee replacement after septic loosening implant loosening.
Patients are included with septic loosening of the primary knee implant and indications for knee-replacement and patients with a temporary spacer implantat consist of an long -term established antibiotic-loaded bone cement (Palacos R + G) or with a novel bone cement (Copal spacem) and also patients with a consecutive re-implantation of a revision hip replacement.
The primary outcome measure is the infection control after one year postoperatively determined by the existence of a stable revision prosthesis without clinical, laboratory and radiological signs of persistent or re-infection.

Brief Summary in Scientific Language

A novel cement spacer is part of a two-arm, prospective, multicenter clinical observationn in a comparision of an established care standard ie a standard used spacer cement will be evaluated with the same treatment algorithm of a two-stage total knee replacement in a follow-up of 12 months.
There will be a review of safety and efficacy of the therapy in infected total knee innovation. Reduce a novel spacer cement without zirconia admixture third-body abrasion problems after total knee-replacemant?

Organizational Data

- DRKS-ID: **DRKS00004357**
- Date of Registration in DRKS: **2012/09/12**

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- 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.: **HV-2011-0011 , Ethik-Kommission an der Medizinischen Fakultät der Universität Rostock**

Secondary IDs

Health condition or Problem studied

- ICD10: **T84.5 - Infection and inflammatory reaction due to internal joint prosthesis**

Interventions/Observational Groups

- Arm 1: **control-arm:**
  Patients are included with septic loosening of the primary knee implant and indications for knee-replacement and patients with a temporary spacer implantat consist of an long -term established antibiotic-loaded bone cement (Palacos R + G) and also patients with a consecutive re-implantation of a revision knee replacement.
  After a confirmed diagnosis of late infection of a knee replacement the first step is the explantation of joint replacement. Within the operation are taken standardized tissue samples for the microbiology and pathology. The surgical debridement includes a careful removal of infected soft tissue and bone tissue. The antibiotic cement spacer is previously prepared intraoperatively prior to the deposit, the cement is introduced into a suitable silicone-knee spacerform. The systemic postoperative antibiotic therapy is adapted to the antibiogram and extends over 4 weeks (2 weeks i.v.and 2 weeks p.o.).
  After a six-week interval is a minimally-invasive sampling (biopsy) performed by peri-implant tissues. In microbiology, the joint fluid and the tissue sample is examined. The pathologist examines the tissue samples histologically. The evaluation of microbiology, histology and clinical laboratory data are available after two weeks.
  Based on these data, the question of persistent infection needs to be clarified. If there is no evidence of an infection the reimplantation is performed.
- Arm 2: **Patients are included with septic loosening of the primary knee implant and indications for knee-replacement and patients with a temporary spacer implantat consist of novel bone cement (Cpoal spacem) and also patients with a consecutive re-implantation of a revision knee replacement.**
  After a confirmed diagnosis of late infection of a knee replacement the first step is the explantation of joint replacement. Within the operation are taken

standardized tissue samples for the microbiology and pathology. The surgical debridement includes a careful removal of infected soft tissue and bone tissue. The novel cement spacer is previously prepared intraoperatively prior to the deposit, the cement is introduced into a suitable silicone-knee spacerform. The systemic postoperative antibiotic therapy is adapted to the antibiogram and extends over 4 weeks (2 weeks i.v.and 2 weeks p.o.).
After a six-week interval is a minimally-invasive sampling (biopsy) performed by peri-implant tissues. In microbiology, the joint fluid and the tissue sample is examined. The pathologist examines the tissue samples histologically. The evaluation of microbiology, histology and clinical laboratory data are available after two weeks.
Based on these data, the question of persistent infection needs to be clarified. If there is no evidence of an infection the reimplantation is performed.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

The primary outcome measure is the infection control after one year postoperatively determined by the existence of a stable revision prosthesis without clinical, laboratory and radiological signs of persistent or re-infection. There are no reliable data for this specific clinical scenario, especially in the German-speaking countries, the study is hypothesis-created.
Within the hip replacement standardized tissue samples are taken for the microbiology and pathology. The explanted prothesis is examined microbiologically. After a six-week interval a minimally-invasive sampling (biopsy) of peri-implant tissues is performed. The joint fluid and the tissue sample are examined microbiologically and the tissue sample is examined histologically.
Within the spacer explantation standardized tissue samples are taken for the microbiology and pathology. The spacer is examined microbiologically.
The quality of life are evaluated by questionnaires (WOMAC, EQ-5D, SF-36) before the intervention and after 3 and 12 months follow-up.

Secondary Outcome

1.Time until the infection recurrence or treatment failure (calculated using Kaplan-Meier analysis, if needed, a multivariate Cox regression) at follow-up

2.Allocation of resources (material costs, hospitalization, number of necessary interventions)
3.Function (measured using the Western Ontario and McMaster Osteoarthritis Index (WOMAC score) and Harris Hip Score) and quality of life (using the EuroQol and SF-36 scores) at follow-up
4.Radiological signs of aseptic or septic loosening of the implant revision during follow-up

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Orthopädische Klinik und Poliklinik, Rostock**
- Medical Center **Südstadtklinikum, Rostock**
- Medical Center **Krankenhaus Bad Doberan, Bad Doberan**
- Medical Center **KMG Klinikum, Güstrow**
- Medical Center **Klinik für Orthopädie, Dietrich-Bonhoeffer-Klinikum, Neubrandenburg-Altentreptow**
- Medical Center **Klinik für Orthopädie, Helios Kliniken, Schwerin**
- University Medical Center **Klinik für Orthopädie und Unfallchirurgie, Klinikum rechts der Isar, TU München, München**
- Medical Center **Helios Hanseklinikum, Stralsund**
- University Medical Center **Universitätsklinikum Klinik und Poliklinik für Orthopädie und Orthopädische Chirugie, Gereifswald**
- Medical Center **Orthopädie, DRK-Krankenhaus Grimmen GmbH, Süderholz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/07/04**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

• aged 50 to 80 years
• diagnosis of septic loosening of knee prostheses with a primary indication for two-stage exchange
• The ability to understand the scope and significance of the study and the willingness and the ability to take part in the following necessary follow-up examinations.
• existence of a written consent form

Exclusion criteria

• presence of a tumor disease
• Known allergy to materials used
• Participation in other studies
• nursing and pregnant women and those women planning to become pregnant during the study period
• non-availability for the duration of the study
• Inadequate knowledge of German (questionnaires)

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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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.*