

Antibiotic impregnated bone graft to reduce infection after revision total hip arthroplasty; The ABOGRAFT trial

Jörg Schilcher¹, Daphne Wezenberg¹, Andreas Meunier¹, Lars Palm¹, Nils P Hailer², Olof Sköldenberg³, Johan Kärrholm⁴, Bo Söderquist⁵

¹ Department of Orthopedic Surgery, and Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden

² Department of Surgical Sciences, Orthopedics Uppsala University, Uppsala, Sweden.

³ Karolinska Institutet, Department of Clinical Sciences at Danderyd Hospital, Division of Orthopaedics, Stockholm, Sweden

⁴ Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.

⁵ Department of Laboratory Medicine, Clinical Microbiology, Faculty of Medicine and Health, Örebro University, Örebro, Sweden.

RATIONALE The risk of infection after revision total hip arthroplasty (rTHA) is much higher compared to that after primary THA. In primary THA, systematic use of antibiotic loaded bone cement has reduced the risk for postoperative infection by half. In rTHA, local antibiotics are not used systematically, and relevant amounts of antibiotic loaded bone cement can rarely be used due to technical limitations. Morselized bone allograft as a carrier for local antibiotics has shown to be effective in rTHA for infection but has never been systematically evaluated as local prophylaxis in the non-infected rTHA.

OUTCOME The primary outcome is the number of reoperations due to infection with bacteria sensitive to vancomycin or tobramycin within 2 years after reoperation.

METHOD This study is a phase II, randomized, double-blind, placebo-controlled, multicenter drug trial. All patients scheduled for reoperation of a THA requiring bone grafting, for any reason other than infection, are eligible for participation (n=1200). Patients are randomized to treatment (vancomycin and tobramycin), or placebo (NaCl) mixed with morselized bone graft (Figure 1). Data on reoperations are collected at 2- and 5-years postoperatively from the Swedish Arthroplasty Register and validated using medical record review (Figure 2).

ANALYSIS The primary outcome will be analyzed using proportional hazard models for the two groups stratified for study site and sex.

PROGRESS Patient recruitment has started in April 2022. After an initial feasibility trial, performed at Linköping University Hospital (20 patients), patient recruitment will be extended to high volume revision centers willing to participate.