POSTOP (Prolia for Osteoporosis of Transplant Operated Patients): A phase 3, investigator-initiated, randomized, open-label single-center study of the effect of denosumab on the prevention of bone mineral density loss after renal transplantation

Original title / Originaltitel
Denosumab zur Prävention der Knochendichteverminderung nach Nierentransplantation

Summary / Zusammenfassung
Osteoporotic fractures represent a major problem after solid organ transplantation. Due to their nephrotoxic potential bisphosphonates have not been widely used in these patients. The purpose of the present study is to test in a randomized clinical trial whether the new anti-osteoporotic drug denosumab (Prolia®) has a beneficial effect on the loss of bone mineral density (BMD) in the first year after renal transplantation (primary endpoint). One hundred newly transplanted renal allograft recipients will be randomized 1:1 to receive either denosumab 60 mg s.c. every 6 month or no therapy. Changes in body height and bone mineral metabolism parameters, incidence of fractures, and allograft function at 1 year will also be assessed. Safety measurements include the occurrence of rejection episodes, graft loss and mortality. This investigator-initiated study will conclusively demonstrate whether denosumab treatment is beneficial in renal transplant recipients. Weitere Informationen unter http://clinicaltrials.gov/ct2/show/NCT01377467

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