Is vancomycin-loaded DAC hydrogel coating of orthopedic implants safe for human use ? Short-term clinical results in two European centers.

- Submission ID 135
- Abstract title (max 20 words)

  Is vancomycin-loaded DAC hydrogel coating of orthopedic implants safe for human use ? Short-term clinical results in two European centers.
- Abstract text max. 400 words (adjust for any figures/tables)

  Aim: Infection remains a leading reason for failure of orthopaedic implants. Among various strategies, aimed at implant-related infection prevention, antibacterial coatings appear an attractive and effective option to prevent bacterial colonization of biomaterials. A fast resorbable (<96 h), antibacterial-loaded hydrogel coating (DAC, Novagenit Srl, Italy), previously tested successfully in vitro and in vivo (1-3), is currently available for clinical use in Europe. Aim of this study was to evaluate the short-term clinical safety of a vancomycin-loaded DAC implant coating in orthopaedics. Methods: In this prospective, single blind study, a total of 58 patients, undergoing total hip or knee prosthesis or osteosynthesis were randomly assigned to receive vancomycin-loaded DAC coating or to a control group, without coating. Pre- and post-operative assessment of laboratory tests, wound healing (ASEPSIS score), clinical score and x-rays was performed at fixed time intervals. Statistical analysis was performed with Fisher exact test or Student's t test. Significance level was set at $p<0.05$. Results: Wound healing, clinical outcome scores, laboratory tests and radiographic findings did not show any significant difference between the two-groups at a mean 6 months follow-up (min: 3, max: 12 months). No early infections of the surgical site were observed in either group and no local or systemic side effects, that could be related to DAC hydrogel coating, were noted. Conclusion: Vancomycin-loaded DAC hydrogel coating appears clinically safe in this first randomised clinical trial evaluating short-term outcome. The study was performed under the multicenter Collaborative Project “I.D.A.C.”, funded by the European Commission, within the 7th Framework Programme on Research Technological Development and Demonstration, grant no. 277988. References: 1. Romanò CL, Giammona G, Giardino R, Meani E (2011) Antibiotic-loaded resorbable hydrogel coating for infection prophylaxis of orthopaedics implants: preliminary studies. J Bone Joint Surg Br 2011 93-B: 337-338. 2. Giavaresi G, Meani E, Sartori M, Ferrari A, Bellini D, Sacchetta AC, Meraner J, Sambri A, Vocale C, Sambri V, Fini M, Romanò CL. (2013) Efficacy of antibacterial-loaded coating in an in vivo model of acutely highly contaminated implant. Int Orthop. 2013 Dec 22. 3. Drago L., Boot W, Dimas K, Malizos K, Hänsch GM, Stuyck J, Gawlitta D, Romanò CL. (2014) Does implant coating with antibacterial-loaded hydrogel reduce bacterial colonization and biofilm formation in vitro ? Clin Orthop Relat Res DOI 10.1007/s11999-014-3558-1.
- Presentation preference

  Oral
- Keyword

  Coating
- Keyword

  Infection
- Keyword

  Implant

- Keyword

Prevention

- Adding figures or tables
- Figure/table 1

cup coating.JPG

- Caption figure 1

Cementless hip prosthesis cup coating with vancomycin-loaded DAC hydrogel

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