

Research Project

Single-Dose Versus 3-Day Cotrimoxazole Prophylaxis in Transurethral Resection or Greenlight Laser Vaporisation of the Prostate: A Pragmatic, Multicentre Randomised Placebo Controlled Non-Inferiority Trial

Third-party funded project

Project title Single-Dose Versus 3-Day Cotrimoxazole Prophylaxis in Transurethral Resection or Greenlight Laser Vaporisation of the Prostate: A Pragmatic, Multicentre Randomised Placebo Controlled Non-Inferiority Trial

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The worldwide increase of antimicrobial resistances has gained international attention and has been labelled by the World Health Organisation as top public health priority. Today, in urological out- and in-patients, multidrug-resistance among main uropathogens such as *Escherichia coli* is increasing rapidly - which can, at least partly, be explained by the well-characterised extended use and over-prescription of antibiotics in daily urological practice, especially for antibiotic prophylaxis (AP) in standard urological procedures. A prolonged course of AP decreases the rate of bacteriuria at the expense of higher rates of adverse drug events, *Clostridium difficile*-associated infections and consecutive antimicrobial resistances. Transurethral resection of the prostate (TURP) is one of the most frequently performed urological procedures, which is conducted in almost 10,000 men annually in Switzerland. However, photoselective vaporisation with the Greenlight Laser (GL) has become an important alternative to TURP, particularly in patients receiving anticoagulation therapy. Generally, urine is sterile, but TURP and GL are performed in an elderly population, where asymptomatic bacteriuria is highly prevalent; therefore, TURP belongs to the category "clean-contaminated" according to the World Health Organisation and consequently, routine AP in TURP is considered as a standard of care. The European Association of Urology and our in-house guidelines recommend routine AP in TURP to decrease the incidence of bacteriuria, bacteraemia, and urinary tract infections (UTIs). But currently, there are no randomised controlled trials and guidelines for AP in patients undergoing GL. In addition, most of the studies for AP in TURP were performed more than twenty years ago - with still a large gap being present between actual clinical practice of AP in TURP and evidence-based guidelines especially in terms of duration of AP. Therefore, we aim to compare the effectiveness of the current clinical practice (usual care with prolonged AP) to guideline-conform single-shot AP with trimethoprim/sulfamethoxazole in patients undergoing TURP and GL. For this purpose, we will conduct a multicentre pragmatic randomised controlled trial analysing the non-inferiority of a single-dose AP on the primary outcome measure of postoperative UTI and urosepsis within 30 days after TURP and GL. The results of this study will help to elaborate guidelines on AP and antimicrobial stewardship in TURP and GL.

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