Stopping or maintaining oral anticoagulation in patients undergoing photoselective vaporization of the prostate (SOAP) surgery for benign prostate obstruction: study protocol for a multicentre randomized controlled trial

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Résumé en anglais	BACKGROUND: Lower urinary tract symptoms related to benign prostatic obstruction (BPO) are frequent in men aged > 50 years. Based on the use of innovative medical devices, a number of transurethral ablative techniques have recently been developed for the surgical treatment of BPO. In recent years, GreenLight photoselective vaporization of the prostate (PVP) has been considered as a non-inferior alternative to transurethral resection of the prostate. The GreenLight PVP is usually considered as an interesting surgical option for patients treated via oral anticoagulants (OACs) with regard to its haemostatic properties. The aim of this study was to assess the impact of maintaining OAC treatment in patients undergoing PVP. METHODS: This study is a multicentre, open-label, randomized controlled trial (RCT) designed to show the non-inferiority of PVP surgery in patients with BPO treated with OACs. This study is designed to enrol 386 OAC-treated patients (treated with vitamin K antagonists and direct oral anticoagulants) who are undergoing PVP for BPO. Patients will be randomized (1:1) to either maintain or stop OAC treatment during the perioperative course. The intervention group will maintain OAC treatment until the day before surgery and resume OAC treatment the day after surgery, whereas the control group will stop OAC treatment (with or without low-molecular-weight heparin bridging therapy) according to the anaesthesia guidelines. The primary outcome of interest to be assessed is the 30-day complications rate according to the Clavien-Dindo classification. The secondary endpoint will examine the 30-day rate of haemorrhagic and thrombotic events. This study will provide 80% power to show non-inferiority, defined as not worse than a 10% (non-inferiority margin) inferior change in the proportion of patients with good outcomes (Clavien-Dindo score < 2), using two-tailed 95% confidence intervals. DISCUSSION: This first multicentre RCT in the field is underway to evaluate the safety and efficacy of PVP in patients with ongoing OAC therapy. The study results could influence the perioperative management of OACs in BPO surgery with a high level of evidence. TRIAL REGISTRATION: ClinicalTrials.gov, NCT03297281 . Registered on 29 September 2017.
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DOI	10.1186/s13063-018-3066-9 [38]
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