



BMJ Open Randomised, quadruple blinded, placebo controlled, multicentre trial investigating prophylactic tamsulosin in prevention of postoperative urinary retention in men after endoscopic total extraperitoneal inguinal hernia repair (STOP-POUR trial): a study protocol

Uwe Bieri ,¹ Juliette Sliker,² Lukas John Hefermehl,³ Sebastian Soppe,² Gerfried Teufelberger,⁴ Regula Tedaldi,⁴ Nicole Graf,⁵ Marco Bieri,⁶ Antonio Nocito ²

To cite: Bieri U, Sliker J, Hefermehl LJ, *et al*. Randomised, quadruple blinded, placebo controlled, multicentre trial investigating prophylactic tamsulosin in prevention of postoperative urinary retention in men after endoscopic total extraperitoneal inguinal hernia repair (STOP-POUR trial): a study protocol. *BMJ Open* 2021;**11**:e048911. doi:10.1136/bmjopen-2021-048911

► Prepublication history for this paper is available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-048911>).

Received 11 January 2021
Accepted 09 November 2021



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For numbered affiliations see end of article.

Correspondence to

Professor Antonio Nocito;
antonio.nocito@ksb.ch

ABSTRACT

Introduction Postoperative urinary retention (POUR) is a common complication after inguinal hernia repair with a reported incidence up to 34%. It can be described as the inability to initiate urination or insufficient bladder emptying following surgery. It usually requires the use of catheterisation to empty the bladder in order to prevent further injury to the bladder or kidneys and to relief from pain. Tamsulosin is a medication that is commonly used in men with urinary symptoms related to an enlarged prostate. There is some evidence to suggest that it may also potentially be beneficial for preventing POUR.

Methods and analysis This is a multicentre, blinded, prospective, phase IV randomised controlled trial with parallel allocation. Six hundred and thirty-four patients scheduled for elective endoscopic inguinal hernia repair surgery will be recruited. There will be effective (concealed) randomisation of the subjects to the intervention/control groups. Group assignment will be performed using a covariate-adaptive allocation procedure to provide a balance for selected covariates. The interventional group receives 0.4 mg tamsulosin hydrochloride and the control-group receives one placebo capsule matching the active study drug, both daily, starting from 5 days prior to the day of surgery, at the day of surgery and for 1 day following surgery. The primary outcome is any need for urinary catheterisation postoperatively as a binary outcome. Secondary outcome measures include postoperative pain, change in International Prostate Symptom Score from baseline prior to surgery to after surgery and hospital stay.

Ethics and dissemination The study has been approved by the Northwestern and Central Switzerland Ethics Committee (2020–00569) and it is being conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Study results will be disseminated through peer-reviewed journals and national and international scientific conferences.

Strengths and limitations of this study

- This is the first randomised controlled and quadruple blinded study to address the prophylactic effect of tamsulosin in preventing postoperative urinary retention in a pure endoscopic inguinal hernia repair cohort.
- Robust design by integrating the pharmacokinetics of the Investigational Medicinal Product (IMP), clearly defined primary and secondary outcomes and a short duration of the study with a follow-up time of only 3 days.
- A blinded interim analysis will be performed when the primary endpoint for 50% of patients is available for the purpose of sample size re-estimation.
- Our relative rigorous definitions of eligibility criteria will limit the extrapolation of our expected findings to a larger population, for example, younger patients or different operation technique.
- Despite the fact that prostate volume is one of the most important predictive factors for the development of urinary retention in general, no prostate volumetry will be performed preoperatively.

Trial registration numbers SNCTP000003904.
NCT04491526.

INTRODUCTION

Background and rationale

Postoperative urinary retention (POUR) is defined as the inability to urinate after an operative procedure with concomitant full bladder. POUR is a common complication occurring after 5%–70% of all operations,¹ especially after inguinal hernia repair with a

reported incidence up to 34%.^{2,3} The standard treatment of POUR is in-out or indwelling urethral catheterisation. There is no standard pharmaceutical treatment of POUR, although alpha-blockers are frequently used to treat POUR, but not as prophylaxis.⁴ POUR may cause pain, prolonged recovery, catheter-related infections or injuries of bladder and urethra, longer hospitalisation and higher overall health costs. Due to insufficient studies in this field, there is no available and acknowledged preventive strategy standard at this moment. A possible prophylactic intervention is the administration of a clinically well-established alpha-blocker with few side effects. The super-selective alpha-blocker tamsulosin is being used as treatment for men with micturition disturbances such as diminished urinary stream in benign prostate obstruction syndrome by interacting with alpha-receptors and reducing the alpha-adrenergic effect, resulting in muscle relaxation. The drug is well tolerated by nearly all patients and has no known serious side effects. A few small pilot studies⁵⁻⁷ have shown a positive effect of tamsulosin on POUR, however it is necessary to conduct a larger, well designed study to confirm these results in patients undergoing endoscopic inguinal hernia repair.

Objectives

The aim of this study is to demonstrate if tamsulosin is superior to placebo on preventing POUR after endoscopic inguinal hernia repair.

Trial design

The STOP-POUR trial is a multicentre quadruple blinded, phase IV randomised controlled trial with parallel allocation, with the need for a postoperative urinary catheter as primary outcome.

METHODS AND ANALYSIS

We used the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist when writing our report.⁸

Study setting

The study is performed at the Cantonal Hospital of Baden (Switzerland) and the Regional Hospital of Muri (Switzerland). The Cantonal Hospital of Baden is accredited as reference centre for hernia surgery by the DGAV (Deutsche Gesellschaft für Allgemein und Viszeralchirurgie), performing approximately 600 hernia surgeries per year. Recruitment for the study started in November 2020, inclusion will be continued until calculated sample size is obtained, expected is an inclusion period of 27 months.

Eligibility criteria

The target population are men ≥ 60 years of age undergoing elective unilateral or bilateral totally extraperitoneal (TEP) inguinal hernia repair, with surgery scheduled more than 6 days from the day of consent.

Exclusion criteria

- ▶ Orthostatic hypotension (feeling of dizziness after getting up from a sitting or lying position).
- ▶ Severe liver disease (Child Pugh C).
- ▶ Taking strong inhibitors of CYP3A4 (ketoconazole, itraconazole, clarithromycin, ritonavir, indinavir/ritonavir, lopinavir or conivaptan).
- ▶ Being on alpha-blockers (alfuzosin, doxazosin, prazosin, terazosin, tamsulosin, phenoxybenzamine or silodosin) or a combination product containing alpha-blocker (duodart).
- ▶ History of allergy or sensitivity to tamsulosin or other alpha-blockers (alfuzosin, doxazosin, prazosin, terazosin or phenoxybenzamine).
- ▶ Operation with urinary or suprapubic catheter.
- ▶ Status post-cystectomy.
- ▶ Inability to provide informed consent.
- ▶ Known or suspected non-compliance, drug or alcohol abuse.
- ▶ Inability to follow the procedures of the study, for example, due to language problems, psychological disorders, dementia of the participant.
- ▶ Participation in another study with investigational drug within the 30 days preceding and during the present study.
- ▶ Previous enrolment into the current study.

Study intervention

Experimental intervention

Tamsulosin hydrochloride 0.4 mg/day will be given from 5 days prior to the day of surgery, at the day of surgery and for 1 day following surgery by oral route. Steady state is reached after 5 days. The plasma peak values at steady state are about two-thirds higher than those after a single dose. Based on this fact, we will begin the application 5 days before surgery and continue until 1 day after surgery to account for the immediate postoperative stress response.⁹⁻¹¹

Control intervention

One placebo capsule matching the active study drug will be given per day from 5 days prior to the day of surgery, at the day of surgery and for 1 day following surgery.

Compliance with study intervention

To monitor compliance with study medication intake, the study team will ask the participants periodically (at the day of surgery and during the follow-up phone call) about their adherence (patient self-report). Pill counting will be performed at the day of surgery and after the completion of the study when the container and the unused drugs are returned as part of the drug accountability protocol. Non-compliance is defined as follows: The patient fails to take the study medications and/or to follow treatment recommendations as prescribed by the study team. The participant will remain in the study and as stated in the statistics section, we will perform an intention-to-treat

(ITT) analysis and a per-protocol (PP) analysis to account for non-compliance.

Description of the endoscopic TEP inguinal hernia repair operation

Patients are asked to void the bladder before going into the operating room. All surgeries are performed under general anaesthesia. For induction of anaesthesia, propofol is titrated intravenously according to patient response (approximately 20–40 mg of propofol every 10 s) until clinical signs indicate the onset of general anaesthesia. Anaesthesia is maintained with a target-controlled infusion of propofol according to the patient's weight, height, age and sex. Analgesia during anaesthesia is provided with fentanyl at a dosage of 2 µg fentanyl per kilogram of body weight (kg/BW) intravenously. Neuromuscular blockade is achieved with atracurium at a dosage of 0.4–0.6 mg/kg/BW intravenously. Reversal of neuromuscular blockade is performed with neostigmine 0.05 mg/kg/BW intravenously and glycopyrronium bromide 0.01 mg/kg/BW intravenously over 10–30 s. For prevention of postoperative nausea and vomiting 4–8 mg of dexamethasone will be administered intravenously after the induction of anaesthesia. During surgery no urinary catheter is used. Through a subumbilical incision the preperitoneal space is created by telescopic dissection and carbon dioxide is insufflated. A second trocar is placed halfway the umbilicus and pubic bone. The space of Bogros is created, and the lateral space of Retzius is opened. A third trocar is placed, standard anatomical landmarks are identified, all sites for potential herniation are examined (direct inguinal/indirect inguinal/femoral/obturator). The hernia is reduced, the spermatic cord freed of peritoneum on a 7 cm length. A Bard 3D XL (12.2×17 cm) Mesh is placed, mesh fixation is performed according to international hernia guidelines. In case of bilateral hernia, the same technique is applied on the other side, using the same three trocars. No routine drainage is placed, this is only performed when deemed necessary by the surgeon due to risk of bleeding. Mesh placement is visually verified during desufflation. Postoperatively patients are admitted to the recovery unit, for post-anaesthesia monitoring. In this unit patients are lying in bed. They are transferred to the normal surgical ward once normal level of consciousness is reached, and no signs of complications are present. In general this is achieved 1.5–2 hours postoperatively. Once arriving on the surgical ward, patients are allowed free mobilisation (including sitting up or standing up). Regarding diet, patients are allowed to drink water once normal level of consciousness is reached in the post-anaesthesia recovery room. Once arriving on the surgical ward patients are allowed free diet. Standard postoperative analgesia consists of paracetamol and metamizole patients scheduled for outpatient treatment (unilateral TEP surgery) are operated on early in the day, the surgical schedule is planned accordingly, and if patients meet discharge criteria, they can go home the same day. In case of POUR, patients stay overnight and are then treated as inpatients.

Patients undergoing bilateral TEP-surgery are treated as inpatients as standard.

Primary outcome

The primary outcome is the need for any urinary catheterisation postoperatively up to 3 days after surgery. The following algorithm is used: if patients have not voided the bladder spontaneously within 3 hours postoperatively, ultrasound assessment of bladder volume is performed. If the bladder volume is ≥600 mL and after an unsuccessful attempt to void spontaneously (15 min), POUR is diagnosed and transurethral catheterisation will be performed. If bladder volume is <600 mL, these steps are repeated with 2-hour intervals until the patient voids spontaneously or catheterisation threshold is reached. Maximal duration of conservative treatment without spontaneous miction is 7 hours, after this duration a urinary catheter will be placed.

Secondary outcomes

- ▶ Time to first voiding after surgery.
- ▶ Volume of first micturition after surgery.
- ▶ Postoperative pain (Numeric Rating Scale 11).
- ▶ Quantity of postoperative opioid use (oral morphine equivalence dose).
- ▶ Quantity of intraoperative opioid use (oral morphine equivalence dose).
- ▶ Amount of intraoperative fluid administration.
- ▶ IPSS (International Prostate Symptom Score) pre-surgery (–5 days).
- ▶ IPSS score post-surgery (+3 days).
- ▶ Change in IPSS from baseline prior to surgery (–5 days) to day 3 (+3 days) after surgery.
- ▶ Side effects of study medication.
- ▶ In-hospital complications.
- ▶ Length of hospital stay in days (inpatients).
- ▶ Time to discharge after surgery in hours (outpatients).

(b) Secondary outcomes in POUR patients

- ▶ Residual urinary volume after catheterisation.
- ▶ Macrohaematuria (presence of visual detectable blood in the urine).
- ▶ Relevant injury to the urethra (presence of a *via falsa* diagnosed by a urologist).
- ▶ Catheter-related infections.
- ▶ Catheter-related bladder discomfort (grading according to the three grades (mild, moderate, severe) defined in the publication by Zugail *et al*¹²).
- ▶ Prostatitis.
- ▶ Failed first trial without catheter (TWOC: need for a second catheter insertion due to insufficient voiding after TWOC).

Participant timeline

The scheduled visits and assessments are described in [table 1](#).

Table 1 Study schedule of visits and assessments

| Study periods | Screening (outpatient clinic) | Treatment period (operation) | Follow-up (telephone) |
|--|-------------------------------|------------------------------|-----------------------|
| Visit | 1 | 2 | 3 |
| Time (day) | ≤ -6 | 0 | 3 |
| Patient information and informed consent | x | | |
| Demographics | x | | |
| Medical history | x | | |
| Inclusion/exclusion criteria | x | | |
| Physical examination | x | | |
| Vital signs | x | | |
| International Prostate Symptom Score | x | | x |
| Randomisation | x | | |
| Dispense study medication | x | | |
| Recollect study medication | | | x |
| Primary variable | | x | x |
| Secondary variables | | x | x |
| Concomitant therapy | | x | |
| Adverse events | | x | x |

Sample size

We anticipate the detection of a 65% relative risk reduction of POUR in the experimental group in comparison with the placebo group, based on conservative assumptions from previous publications.⁵⁻⁷ To detect a 65% reduction of POUR in the experimental group (2.9% anticipated) in comparison with the placebo group (8.3% anticipated) and to assure a study power of 80% with a Fisher's exact test and a significance level of 5% and adjusting for a dropout rate of 2% we need 634 patients in total; 317 in each group.

Recruitment and screening

Every patient referred for surgical consultation prior to an endoscopic inguinal hernia repair will be screened. If the patient is eligible for participation in the study, he will be informed and will receive the patient information document. After giving informed consent, the patient has at least 1 day time for consideration. There will be no financial compensation to study participants.

Sequence generation and randomisation

A block randomisation (block size of four) with a dummy stratification (stratum A and B) will be used in a first step.¹³ Thus, patients will be randomly assigned to either stratum A or B. In stratum A, patients will be allocated to the tamsulosin group with a probability of 0.2 and to the placebo group with a probability of 0.8. In stratum B, patients will be allocated to the tamsulosin group with a probability of 0.8 and to placebo group with a probability of 0.2. The allocation to the tamsulosin and placebo group will be performed using a covariate-adaptive allocation procedure to provide a balance for selected covariates: Site (Baden, Muri), IPSS (0-7; 8-19; 20-35), age (60-65;

66-70; 71-75; 76-80; 81-85; 86-90; >90), history of prostate surgery (yes/no). To achieve that, minimisation will be applied. First described by Taves¹⁴ and expanded by Pocock and Simon,¹⁵ it is the most commonly used covariate-adaptive randomisation method.

Concealment mechanism and blinding procedures

Because it is not feasible to obtain placebo capsules identical to tamsulosin mepha capsules, the Central Pharmacy (Kantonsapotheke Zürich) provided a placebo ingredient (maize starch) for the study, and both tamsulosin mepha and the placebo ingredient were embedded in a hard gelatin capsule with an identical appearance, matching shape, size, colour and texture. All study subjects will be provided with identical dosage instructions. Central teams (employees of the pharmacy) not involved in the design and performance of the study, will pre-pack active and placebo treatments in study doses and store the package for each patient in a sealed numbered container. Quadruple blinding (participant, care provider, investigator, outcomes assessor) will be ensured during the entire study period.

An emergency code break will be available to the investigator. This code break would be opened only in emergency situations when the identity of the investigational product must be known by the investigator in order to provide appropriate medical treatment.

Data management system

For the present clinical study, the electronic data capture software "secuTrial" (interActive systems; iAs, Berlin) will be used for data processing and management. Data recording and entry will be performed by trained study personnel (investigators and study nurses).

Statistical methods

Planned analyses

The statistical analysis will be done by Graf Biostatistics after database lock. All hypotheses will be tested with two-tailed tests. A p value of 0.05 or less for the primary endpoint will be considered evidence of statistical significance. The secondary endpoints are intended to yield supportive evidence related to the primary objective. Reported p values for secondary endpoints will be considered nominal and unadjusted for multiple testing, without conclusions regarding statistical significance.

Data sets to be analysed

For the analysis of all endpoints, all randomised subjects with valid data will be analysed. Missing data will not be replaced as it is expected that the number of missing values will be low. Both an ITT analysis and a PP analysis will be performed and reported. For some variables such as catheterisation associated outcomes, only those patients can be included in the analyses for obvious reasons who have had a catheterisation. For the analysis of safety, all randomised and treated patients will be analysed. The safety population will be analysed according to the actually administered treatment.

Primary analysis

The primary endpoint, that is, the need for catheterisation, will be analysed with a Fisher's exact test. As a sensitivity analysis, the primary endpoint will also be analysed with a logistic regression controlling for site, baseline IPSS, age and history of prostate surgery.

Secondary analyses

Continuous endpoints will be compared between the treatment groups with an independent samples t-test or a Mann-Whitney U test according to the distribution of the data. Categorical variables will be compared between the treatment groups with a χ^2 test or Fisher's exact test.

Monitoring

Monitoring will be performed by one person, independent of the study organisers. The extent and nature of monitoring activities based on the objective and design of the study are defined in a study specific monitoring plan.

Audits and inspections

A quality assurance audit/inspection of this study may be conducted by the competent authority or central ethics committee (CEC), respectively. The quality assurance auditor/inspector will have access to all medical records, the investigator's study related files and correspondence and the informed consent documentation that is relevant to this clinical study.

Interim analyses

An interim analysis will be performed when the primary endpoint of a total of n=310 patients is available. This interim analysis will be done for the purpose of sample size re-estimation. The patients' treatment codes will

remain masked and only the pooled event rates for each stratum will be reported. According to Shih and Zhao¹³ the true event rates in each treatment group can be calculated by the following formula:

$$\hat{p}_1 = \frac{\pi\hat{\theta}_1 - (1-\pi)\hat{\theta}_2}{2\pi-1}$$

$$\hat{p}_2 = \frac{\pi\hat{\theta}_2 - (1-\pi)\hat{\theta}_1}{2\pi-1}$$

where π is the allocation probability of 0.2 and $\hat{\theta}$ is the observed event rate in each stratum.

A sample size re-estimation will then be performed with the true event rates. If $\hat{n} > n$ the sample size can be increased to a maximum of 400 per group. If $\hat{n} < 0.6n$ the sample size can be decreased to a minimum of 200 per group. Simulation results by Shih and Zhao¹³ showed that there is only a slight effect on the type I error rate by this design. Moreover, Friede and Kieser¹⁶ argue that the Fisher's exact test maintains the correct nominal level under any blinded sample size adjustment procedure.

Safety

During the entire duration of the study, all adverse events and all serious adverse events are collected, fully investigated and documented in source documents and case report forms. Regarding side effects of tamsulosin, 'feeling of dizziness' and 'abnormal ejaculation' have a known frequency of >1%–<10%. These side effects will be recorded with active questioning.

Confidentiality

For data and query management, monitoring, reporting and coding an internet-based secure database "secuTrial" developed according to the Good Clinical Practice (GCP) guidelines provided by the Clinical Trials Center Zurich will be used for this study.

Patient and public involvement

Neither patients nor public were involved in the development of the study.

ETHICS AND DISSEMINATION

Ethics

The study will be carried out in accordance with principles enunciated in the current version of the Declaration of Helsinki, the guidelines of GCP issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, and Swiss competent authority's requirements. CEC and competent authorities will receive annual safety and interim reports and be informed about study stop/end in agreement with local requirements. Each substantial protocol amendment will be notified for approval to the CEC prior to implementation. All participants for this study will be provided a participant information sheet and a consent form describing this study and providing sufficient information for participants to make an informed decision about their participation in this study.



Dissemination plan

It is our intent to present the scientific findings as oral communications and abstracts at national and international scientific meetings related to general surgery, hernia repair and urology. We also plan to publish our findings in peer-reviewed journals of the corresponding subspecialties. De-identified participant data are available on reasonable request from <https://orcid.org/0000-0002-7339-1458>.

Author affiliations

¹Department of Urology, University Hospital Zurich, Zurich, Switzerland

²Department for General, Visceral and Vascular Surgery, Kantonsspital Baden, Baden, Switzerland

³Department of Surgery, Division of Urology, Kantonsspital Baden, Baden, Switzerland

⁴Department of General Surgery, Spital Muri, Muri, Switzerland

⁵Graf Biostatistics, Winterthur, Switzerland

⁶Commissioning and Qualification Engineer, Rotkreuz, Switzerland

Twitter Uwe Bieri @UweBieri

Contributors UB, JS, LJH and AN wrote the study protocol. AN is the principal investigator for this study. JS is responsible for the running of the clinical trial and is the coordinating-investigator. GT is the local principal investigator at the Muri Site. RT is the co-investigator at the Muri site. UB drafted the protocol in the journal format. SS is the coordinator of the certified hernia centre and responsible for the performance of the surgeries according to the world guidelines for hernia management. MB developed the monitoring plan, wrote the monitoring section in the study protocol and is responsible for the monitoring of the study. NG developed the statistical plan and wrote the statistical section in the study protocol. All authors have contributed to the revision of the manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iDs

Uwe Bieri <http://orcid.org/0000-0002-7339-1458>

Antonio Nocito <http://orcid.org/0000-0002-6062-2077>

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