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## *FANS vs sheathless URS lithotripsy - a prospective, randomised clinical trial*

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**The authors' contributions to the study:**

Ø Ulvik is the project manager and is responsible for the overall progress of the study. He will write the study protocol, making the data registration forms, patient information and consent forms, apply for approval by The National Committees for Research Ethics in Norway and The Data Protection Authorities at Haukeland University Hospital (HUH). In addition, Ulvik will apply for registration in the clinical research database for randomized trials, ClinicalTrials.gov. Ulvik will also be doing the ureteroscopies (URS) and follow-up in the study patients, data sampling and take part in the statistical analyses. In addition, he will contribute to the draft and supervise the writing process of the manuscript. He will also be the main supervisor for Tegnander during the study.

MS Æsøy and A Tegnander are, together with Ø Ulvik, the main investigators and will take part in all processes of the study (development of registration forms, follow-up of the patients, data sampling, statistical analyses). Æsøy will be the first author of the main article

and A Tegnander will be first author of the second article comparing high and low laser settings with FANS. They are responsible for making the draft, revisions and writing the final manuscript.

MS Æsøy will also take part in the full process of the study (development of registration forms, contribute to the data collection, performing the URSs and follow-up, statistical analysis, drafting of the manuscript, revisions in addition to critical review of the final version. He will also serve as a co-supervisor for Tegnander during the study process.

D Helgø will perform the URSs at Akershus University Hospital (AHUH), follow-up and collection of data. He will also perform critical review of the manuscript draft.

SE Øverby will perform the URSs at Vestfold Hospital Trust (VHT), follow-up and collection of data. He will also perform critical review of the manuscript draft.

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### **Background:**

The past 30 years, the number of ureteroscopic procedures for stone treatment has risen worldwide <sup>1</sup>. The Holmium: yttrium-aluminium-garnet laser (Ho:YAG) has been considered the *gold-standard* laser for URS because of its versatility, with the ability to break all kinds of stones in the urinary tract as well as tumour- and soft tissue ablation <sup>2</sup>. In 2020, a new Thulium fibre laser (TFL) was introduced for clinical use. The pulsed infrared light emitted by the TFL has a wavelength of 1940 nm which is close to the water absorption peak, and the energy delivered by this laser is therefore highly absorbed by water. High water absorption corresponds to low threshold for tissue ablation and stone lithotripsy <sup>3</sup>. Due to the physical characteristics, the TFL was expected to be very efficient at disintegrating stones. In a laboratory setting TFL has been proven to produce finer dust particles compared to Ho:YAG laser <sup>3</sup>. Previous pre-clinical studies have also predicted TFL lithotripsy to be up to four times faster than Ho:YAG lithotripsy using the same power settings <sup>4</sup>.

In 2022 we published the first clinical randomised trial comparing the outcomes after ureteroscopic lithotripsy using TFL and Ho:YAG <sup>2</sup>. The study demonstrated superior stone free rate (SFR) for TFL compared to Ho:YAG, in addition to lower complication rate and shorter operative times. Based on the results from our study, we believe the TFL is emerging as the laser of choice. Furthermore, the study also proved very low laser settings to be highly efficient using TFL during URS lithotripsy <sup>2</sup>. However, no consensus exists on the preferred

laser settings for the TFL during this procedure, and a variety of different settings have been suggested included high power settings as high as 45 Watts <sup>5</sup>.

Although endourology experts around the world use different settings for TFL lithotripsy, concern has been raised when high power settings have been applied owing to the observed rise in intrapelvic temperatures. We did therefore investigate temperature profiles during URS laser activation with different lasers (TFL and Ho:YAG), laser settings and fibre sizes in a pre-clinical study <sup>6</sup>. The results showed that the rise in temperature in the renal pelvis was negligible when low settings below 8 Watts were used, even when the laser was activated continuously for 180 seconds. However, applying laser settings of 20 Watts resulted in a significant rise in temperature and the threshold for heat induced cell injury (43°C) was reached and exceeded after approximately 40-45 seconds of continuous laser activation depending on the size of the fibre. Using smaller fibres extended the time before 43°C was reached <sup>6</sup>. Recently, the results have been verified in a clinical setting <sup>7</sup>. Using a similar set up for temperature measurement, ten patients with ureteral stones drained with nephrostomy tubes were included. Different laser settings were applied to break the stone after being pushed back into the renal pelvis. The threshold of 43°C was reached in three patients using 20 Watts and in eight patients using 30 Watts. Furthermore, the fastest time until the temperature threshold of 43°C was reached was 12 and 28 seconds using 30 Watts and 20 Watts, respectively. In comparison, 43°C was never reached using 5 Watts and 10 Watts even when the laser was activated for 120 seconds continuously <sup>7</sup>. As a conclusion, laser settings should be kept < 20 Watts to avoid thermal injuries using a sheathless approach. Critics of the randomised study comparing Ho:YAG and TFL have claimed suboptimal and too low laser settings were applied <sup>8</sup>. Even though the criticism missed the target for the specific study <sup>9</sup>, there is still an ongoing debate of the most effective laser settings during URS lithotripsy. However, randomised trials and reviews have shown no superiority in SFRs, operative times or complication rates for low power or high power settings using Ho:YAG lasers <sup>10,11</sup>. Until recently, no clinical randomised trials comparing different laser settings for TFL existed. However, we performed a randomised trial comparing low and high power TFL URS lithotripsy to determine the optimal laser settings with regards to clinical outcomes. The study was the first randomised clinical trial of its kind comparing different TFL settings in URS lithotripsy and was published just a few months ago <sup>12</sup>. In this study, patients with renal stones 8 – 25 mm were randomised to URS TFL lithotripsy with 4 – 6 Watts (low power) or

16 – 18 Watts (high power). As a sheathless approach was used in both arms, the settings were decided based on the settings used in previous trials and the temperature studies to ensure effective lithotripsy and avoid thermal injuries <sup>2,6,7</sup>. The study showed no difference in operative times between the groups, however, significantly higher SFR and lower complication rates were achieved in the low power group compared to the high power group <sup>12</sup>. The results are partly explained by impaired endoscopic visibility caused by the «snowstorm effect» seen when high power dusting is performed. The effect demands frequent breaks in laser activation to clear the visibility thereby prolonging operative time, as well as increase the risk of fragments being hidden in dust causing lower SFR <sup>13</sup>. Again, criticism has been raised as only a sheathless approach was used in the randomised comparison between low power and high power settings. Although applying ureteral access sheaths (UAS) does not seem to influence the clinical outcome after URS lithotripsy significantly, the recently introduced flexible and navigable suction access sheaths (FANS) have shown promising results <sup>14,15</sup>. Adding suction to the access sheath is thought to be beneficial in clearing the calyces and renal pelvis for dust and small particles that otherwise would be left for spontaneous passage. In addition, introducing suction will increase the irrigational shift and reduce intrarenal pressures, thereby lowering the thermal effect of laser usage and the risk of infectious complications. A recently published randomised trial comparing URS lithotripsy with traditional UAS and FANS showed significantly better outcome in the FANS group regarding SFR and postoperative fever <sup>16</sup>. Of note, the 3 months SFR achieved using traditional UAS in this study was 70%. In comparison, the SFR for sheathless URS using low power in our RCT was 77% using the same definition of stone free (Grade B, no residuals  $\geq 2$  mm) <sup>12</sup>. To date, there is no randomised studies comparing the clinical outcomes after URS lithotripsy using FANS and a sheathless approach.

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**Aims of the study:**

The primary aim of the planned study is to compare SFRs following URS lithotripsy for renal stones with TFL using a sheathless approach and with FANS.

Secondary aims are to compare the results of sheathless- and FANS assisted URS lithotripsy in terms of operative time, laser time, intraoperative and postoperative complications.

Following the primary comparison between sheathless and FANS groups, in prespecified secondary analysis another aim is to compare the outcome of low power and high power URS lithotripsy in the FANS patients with respect to operative time, SFR, laser time, intraoperative and postoperative complications.

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**Hypotheses:**

1. The SFR, defined as zero residual fragments (Grade A) detected on CT scan 3 months after the URS, is higher following TFL lithotripsy with FANS compared to sheathless URS. The corresponding  $H_0$  is that *“there is no difference in SFR following laser lithotripsy with FANS and sheathless URS.”*
2. Operative time following URS TFL lithotripsy with FANS is shorter compared to sheathless URS.  $H_0$ : *“There is no difference in the operative time between TFL lithotripsy using FANS and sheathless URS.”*
3. Lasering time is shorter for TFL lithotripsy using FANS compared to sheathless URS.  $H_0$ : *“There is no difference in the lasering time between FANS and sheathless URS.”*
4. There are less intraoperative complications during TFL lithotripsy with FANS compared to sheathless URS.  $H_0$ : *“There is no difference in intraoperative complications between FANS and sheathless URS.”*
5. There are less postoperative complications (infections, readmissions, strictures) after TFL lithotripsy with FANS compared to sheathless URS.  $H_0$ : *“There is no difference in postoperative complications after FANS and sheathless URS.”*

For the subgroup analyses comparing low power and high power laser settings in the FANS groups, the following hypotheses apply:

6. Operative time following TFL lithotripsy with high power settings is shorter compared to TFL lithotripsy with low power settings.  $H_0$ : *“There is no difference in the operative time between low and high power settings.”*

7. The SFR, defined as no residual fragments (Grade A) detected on CT scan 3 months after the URS, is higher following lithotripsy with high power settings compared to low power settings. The corresponding  $H_0$  is that *“there is no difference in SFR following laser lithotripsy with high power and low power laser settings.”*
  8. Lasering time is shorter for TFL lithotripsy using high power settings compared to low power settings.  $H_0$ : *“There is no difference in the lasering time between low and high power laser settings.”*
  9. There are less intraoperative complications during TFL lithotripsy with low power compared to high power settings.  $H_0$ : *“There is no difference in intraoperative complications between low and high power settings.”*
  10. There are less postoperative complications (infections, readmissions, strictures) during TFL lithotripsy with low power compared to high power settings.  $H_0$ : *“There is no difference in postoperative complications between low and high power.”*
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### **Study design:**

The study is planned as a prospective clinical randomized trial. Patients  $\geq 18$  years scheduled to URS lithotripsy for renal stones, 8 – 25 mm, at the day surgery unit at HUH, AHUH and VHT are invited to be enrolled in the study. After written informed consent, patients are randomised to one of three groups: A) sheathless URS TFL lithotripsy with low power settings, B) URS TFL lithotripsy with FANS using low power laser settings, or C) URS TFL lithotripsy with FANS using high power laser settings.

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### **Randomization:**

The randomization is performed electronically with the same number of patients in each group (1:1:1). The results of the randomization are being kept in sealed and consecutively numbered envelopes that is opened just before starting the endoscopic procedure in each

patient. Alternatively, randomisation may be performed electronically in REDCap, a program also used for registration of data.

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### **Patients and data sampling:**

All patients  $\geq 18$  years scheduled for URS lithotripsy for renal stones, 8 – 25 mm, at the day surgery unit at HUH, AHUH and VHT are eligible for inclusion in this study. Only patients with renal stones can be included. Patients with combined ureteral- and renal stones are excluded. The number of patients/procedures needed to be included in the study is specified in the Power analysis-section below.

The following data need to be registered:

- *Preoperative status:* Age, sex, ASA-status, stone status, acute/planned surgery, pretesting-status, infection.
- *Peroperative characteristics:* Randomization status, primary surgeon, antibiotic prophylaxis, operative time (start/end time), deployment of FANS, need for balloon dilatation, impacted stone, successful access to the stone, laser settings, laser time (including time of first and last laser activation) and energy used, surgeon's assessment of post endoscopic stone free status, complications, placement of JJ-stent and assessment of endoscopic visibility (Likert scale).
- *Postoperative status:* Length of hospital stay, immediate complications that need urgent treatment, complications after discharge requiring readmission, 3-months follow-up with CT scan (SFR, stricture rate).

The data will be plotted in electronic registration forms (Pdf or REDCap). Completed registration-forms are exported to a SPSS database for statistical analyses.

The registration-forms and the database will be stored at each participating hospital's research servers in a designated file assigned from the Data Protection Officer. An ID-Key file combining personal ID to the registration form will be stored at a designated server for this purpose at each hospital's research servers. Only the local project managers (Øyvind Ulvik, Dan Helgø and Stein Egil Øverby) will have access to the ID-Key file at their respective hospitals.

If a REDCap solution is decided, all registration forms from all three hospitals will be stored in a secure server connected to Helse-Bergen. REDCap generates ID-number automatically. However, an ID-Key file needs to be generated manually at each recruiting hospital and stored locally at a designated research server.

The registration forms and the ID-Key files will be kept on the hospitals' respective servers for five years after the study has been completed in accordance with the law. After five years the data will be made anonymous in terms of deleting the ID-Key file.

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### **Power analysis and sample size calculation:**

In the planned RCT we intend to compare three different treatment arms: A) sheathless URS TFL lithotripsy with low settings, B) URS TFL lithotripsy with FANS using low power laser settings, or C) URS TFL lithotripsy with FANS using high power laser settings. In the first part of the study the primary aim is to compare SFRs between the sheathless URS group and the two groups of FANS combined. In the second part of the study, or the subgroup analyses, we intend to compare low power and high power laser settings in the FANS groups. For simplicity, two separate power analyses will therefore be made. The patients in the FANS groups will be included in both the analyses comparing sheathless and FANS, and the analyses comparing low and high laser settings using FANS. On the other hand, patients in the sheathless group will only be included in the analyses comparing sheathless URS and FANS groups combined.

In our previous RCT comparing low and high TFL laser settings, we found grade A (zero fragment) SFR 3 months after the procedure of 63% in the low power group<sup>12</sup>. In the study by Zhu and co-workers, only grade B SFR after 3 months in the FANS group of 87% was given

<sup>16</sup>. We anticipate that grade A SFR in the FANS group in the planned RCT will be slightly lower, or approximately 85%. Comparison of SFRs between sheathless and FANS groups is done performing a  $\chi^2$ -test. The  $\alpha$  error probability is set to 0.05 and the power (1- $\beta$  error probability) is set to 0.8.

Using IBM SPSS Statistics 31 for power analysis, the number of participants in each group is calculated to be 62.

For the subgroup analyses comparing low and high power laser settings in the FANS groups, we anticipate shorter operative time when high power is applied. No information about the laser settings nor operative time were available from the FANS study by Zhu et al <sup>16</sup>.

However, in our RCT using low laser settings (4-6 Watts) the mean operative time during sheathless URS was 54 minutes <sup>12</sup>. As in that study, a difference in operative time of  $\geq 10$  minutes is considered clinically relevant. A  $\geq 10$  minutes reduction would meaningfully affect operating room workflow, turnover, and day-case scheduling. Smaller differences are considered unlikely to have practical clinical impact. Equal standard deviation of 20 minutes is assumed for both arms <sup>12</sup>. We expect the high power settings during TFL lithotripsy to be more efficient in clearing stones compared to the low power settings, with operative times of approximately 44 and 54 minutes for the two settings, respectively. Comparison of the operative times between low and high power settings will be done using the independent samples *t*-test. The  $\alpha$  error probability is again set to 0.05 and the power (1- $\beta$  error probability) to 0.8.

Using IBM SPSS Statistics 31 for power analysis, the number of participants in each group for this comparison is calculated to be 64.

Combining the sample size calculations and considering that the FANS patients can be used for both analyses, total sample size is calculated to be 62, 64 and 64 in the sheathless group, the FANS group using low power and the FANS group using high power, respectively. To compensate for possible non-evaluable patients, a total of 225, i.e. 75 patients in each group, are planned for inclusion in the study.

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**Statistical analyses:**

Statistical analyses will be performed using IBM SPSS Statistics 31 or higher (IBM, Armonk, NY). A  $p$ -value  $< 0.05$  will determine statistical significance.

Continuous variables will be compared using independent-samples  $t$ -tests, or in the cases where a normal distribution is not met, Mann-Whitney U test. Exact  $\chi^2$ -test test and Fisher's Exact test are used comparing categorical variables.

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**Ethical considerations, ethical approval and patient consent**

Sheathless or «*naked*» URS has been the preferred strategy at HUH for decades, and we have proven the efficacy and safety of the method in several studies <sup>2,12,17,18</sup>. Recently, however, a flexible and navigable suction access sheath (FANS) has been introduced to improve clinical outcomes <sup>15</sup>. Applying suction may be beneficial in clearing the calyces and renal pelvis for dust and small particles that otherwise would be left for spontaneous passage. In addition, introducing suction will increase the irrigational shift and reduce intrarenal pressures, thereby lowering the thermal effect of laser usage and the risk of infectious complications. Furthermore, in a multicentre RCT applying FANS resulted in significantly better outcome compared to traditional UAS regarding SFR and postoperative fever <sup>16</sup>. Despite both a sheathless approach and FANS are being in daily use around the world, no consensus exists of what is considered the preferred strategy. To this end, no randomized clinical trials comparing the outcome of sheathless and FANS URS lithotripsy have been published. The planned study therefore seems to be highly clinically relevant. In addition, participating in this study should not expose patients to extra risk of harm as both strategies are in regular use. The surgical procedures will be performed as planned with no extra risk or discomfort for the patient, and no extra time needed for treatment.

Applications for approval by The National Committees for Research Ethics in Norway and The Data Protection Authorities at HUH, AHUH and VHT will be sent prior to study start. In addition, the study will be registered in the clinical research database for randomized trials, ClinicalTrials.gov.

All patients eligible for inclusion in the study will receive oral and written information.

Participation in the study is voluntarily, and the patient can choose to withdraw at any point during the study process. Inclusion in the study will only be done after the consent form is

signed. The patient information and consent form used for this purpose is obtained from The National Committees for Research Ethics in Norway's website ([https://helseforskning.etikkom.no/frister/malforinformasjonsskriv?p\\_dim=34672](https://helseforskning.etikkom.no/frister/malforinformasjonsskriv?p_dim=34672)).

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### **Patient monitoring during the study process/security committee**

An independent and dedicated group (Christian Moen and Bjarte Almås) will monitor the patients and the results during the study process. Interim analyses will be performed halfway through the study inclusion to ensure efficacy and safety for the patients. The study will be terminated if unacceptable low SFR (< 50%) or high complication rates (> 20% Clavien-Dindo  $\geq 3$ ) are detected in any of the groups. If the criteria for early termination are not met, the study will continue according to plan without informing the investigators about the results of the interim analyses.

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### **Definitions, the URS procedures and follow-up**

Patients with renal stones (8 – 25 mm) planned for URS at the Day Surgery Clinic at HUH, at AHUH and VHT are eligible for inclusion in the study. Patients with concomitant ureteral stones are not eligible for inclusion. The stones are measured on preoperative non-contrast CT in *bone window*. The widest diameter of the largest stone is registered as well as total stone volume. Stone volume is calculated using the formula  $0.52 \times \text{diameterA} \times \text{diameterB} \times \text{diameterC}$  (a simplification of the ellipsoid formula  $V = \frac{4}{3}\pi abc$ , where  $abc$  represent the three different radiuses in the ellipsoid [ $abc = r^3$ ]).

The URS procedure is performed in general anaesthesia and prophylactic antibiotics prior to surgery start will be administered according to the departments' guidelines, either according to urine culture or current local regime. Only endourologists with experience using FANS can perform the URS procedures in the study.

The procedure starts with flexible URS using the 7.5Fr single use MacroLux CoralView flexible ureteroscope with 6.7Fr wedged tip. Cystoscopy may be performed if considered necessary as well as semirigid ureteroscopy. A safety guide wire can be used at the surgeon's discretion but is routinely omitted during URS at the three hospitals. Balloon dilatation (4-5 mm) is

performed on demand. However, multiple dilatations at different levels in the ureter should be avoided. Instead, a JJ-stent should be placed and the patient scheduled for a second procedure. If the patient is scheduled for a second procedure, they keep their allocated treatment group according to the first randomisation. Only the specific MacroLux flexible ureteroscope can be used for the endoscopic lithotripsy. Room-tempered (23°C), gravitational irrigation fluid at 60 cm height is used throughout the procedure when performing a sheathless approach, and gravitational irrigation at 100 cm height when FANS are applied.

Patients are allocated to the randomisation group immediately once the entire ureter is inspected and confirmed stone free. Allocation to randomisation group is done either by opening the sealed envelope revealing the result of the randomisation or by allocation in REDCap. FANS can be placed according to randomisation group only after performing initial endoscopy ensuring no stones are present in the ureter. The size of the FANS must be 9.5/11.5 Ch in the present study in the two FANS groups. However, if placement of a 9.5/11.5 Ch FANS fails an 8.5/10.5 Ch FANS can be attempted. Balloon dilatation can be performed as described above if deemed necessary. If placement of a FANS fails, the patient should still be included in the study but registered as failed access. However, only per protocol analyses will be performed as it is of interest to explore the risk of failed placement of the sheaths. If a second procedure is planned, this should be performed according to the initial randomisation allocation group. The amount of suction applied to the FANS can be adjusted according to the surgeons' discretion. A 150µm sized laser fibre must be used for stone disintegration for all patients across the randomisation groups. The stone is disintegrated using TFL with predefined settings as described below and according to the randomization group. To make the procedures as similar as possible, the stone should be dusted/disintegrated to as small particles as possible rather than fragmented and retrieved. Only residual particles not suitable for further disintegration can be retrieved at the end of the procedure to render the patient stone free.

A JJ-stent can be placed after the procedure if deemed necessary, and if so, this is removed according to standard routine after 1-2 weeks in the outpatient clinic or by the patients themselves if on a string. Follow-up with CT is performed at 3 months post endoscopically for all patients to assess stone free status and exclude a ureteral stricture in addition to a clinical consultation.

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## Laser settings

The laser settings in the three study groups are standardized and need to be maintained throughout the procedure.

|                                                                |                                                              |
|----------------------------------------------------------------|--------------------------------------------------------------|
| <b><i>Group 1 – sheathless (4-10W), short pulse:</i></b>       | 0.4 – 0.5J at 10 or 20Hz<br>0.6 – 0.8J at 10Hz               |
| <b><i>Group 2 – FANS low power (4-10W), short pulse:</i></b>   | 0.4 – 0.5J at 10 or 20Hz<br>0.6 – 0.8J at 10Hz               |
| <b><i>Group 3 – FANS high power (16-24W), short pulse:</i></b> | 0.4 – 0.5J at 40Hz<br>0.6J at 30 – 40Hz<br>0.8J at 20 – 30Hz |

Standard start-up settings: Group 1 (sheathless, low power) 0.4J/10Hz (4W), Group 2 (FANS, low power) 0.6J/10Hz (6W) and Group 3 (FANS, high power) 0.4J/40Hz (16W).

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## Study progress

The date for completing the data registration form, patient information and consent form, and application for approval by The National Committees for Research Ethics in Norway is set to April 1<sup>st</sup>, 2026.

After achieving ethical approval, application for approval from The Data Protection Authorities at HUH, AHUH and VTF will be sent. Prior to enrolment the study also needs to be registered in the clinical research database for randomized trials, ClinicalTrials.gov.

Inclusion of patients and ureteroscopies are expected to start in June 2026, and the inclusion is expected to close during January 2027.

Data analyses and writing a draft is set to spring 2027. Final manuscript ready for submission is planned during the summer 2027.

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## Costs and funding

The study is planned carried out as part of the regular operative schedule at the participating hospitals. Because of this, the project can be completed within regular working hours at HUH and the University of Bergen, AHUH and VTF.

The single use flexible ureteroscopes from MacroLux and the 10/12CH FANS planned for this study has a total prize of approximately NOK 5 000,- per endoscope including one FANS. The total equipment-cost for each hospital when including 75 patients is estimated to be approximately NOK 365 000,-. Each participating hospital is responsible for paying their own costs related to the study.

At HUH, reward funds of NOK 75 000,- will cover some of the cost. In addition, application for research funds of NOK 75 000,- will be sent to the University of Bergen. Similar research funds can be applied for at the other participating hospitals.

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## Conflicts of interest

Øyvind Ulvik and Mathias Sørstrand Æsøy are consultants for Olympus, who has not been involved in any part of planning of this study and will not be involved in any part of the execution of the stud, such as the design, collection, analyses, interpretation or reporting of the data. The remaining authors have nothing to disclose.

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## Publication of data

The results of the study are planned published as a manuscript in an international urological journal (*European Urology*, *BJUI* or equivalent journal). Parts of the results may also be presented at international congresses. All co-authors stated in this protocol will also be included as co-authors in every presentation or publication related to this study.

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Bergen 25.03.2026



Øyvind Ulvik

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