Clinical Study Protocol

Register Randomized Controlled Trial

Laparo-endoscopic Bilateral Inguinal Hernia Repairs

BILAP HERNIA Trial

TRIAL INFORMATION

Principal investigators

Maria Melkemichel

MD, PhD

Department of Clinical Science and Education, Södersjukhuset, Karolinska Institutet. Sweden

Department of Breast, Endocrine tumors and Sarcoma, Karolinska University Hospital, Stockholm, Sweden

Email: maria.melkemichel@ki.se

Phone: +4670 159 7660

Hanna De La Croix

MD, PhD, Associate Professor

Department of Surgery, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

Department of Surgery, Sahlgrenska University Hospital, Region Västra Götaland, Gothenburg, Sweden

Email: hanna.nilsson@gu.se

Phone: +4670 516 57 84

Co-investigators

Ramia Stolt, MD, Ursula Dahlstrand, MD, PhD, Henrik Holmberg, biostatician, associate professor, Johanna Österberg, MD, PhD, Pär Nordin, MD, Professor, Gabriel Sandblom, MD, associate professor

Adjunct members: Filippa Widman, MD

Trial Title

A register-based randomized controlled multicenter trial of laparo-endoscopic bilateral inguinal hernia repairs with an asymptomatic contralateral hernia

Trial Code

BILAP HERNIA Trial

Trial Registration Number

ClinicalTrials.gov Identifier: Not yet registered

Site-Ivestigator's and Trial Surgical units

All surgical departments in Sweden that are participating in the Swedish Hernia Register and that will meet the surgical volume criteria for laparo-endoscopic groin hernia repairs will be invited to include patients.

Trial Period

Estimated start of inclusion: 2026/2027
Estimated end of inclusion: 2030/2031

Ethics

Approval of the study protocol will be obtained by the Regional Ethics Review Board in Sweden prior to inclusion. All procedures performed in the study involving human participants will be in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Participating investigators have the responsibility to give both an oral and a written patient information about the trial. Obtained signed informed consent from all patients are maintained before including them in the trial.

BACKGROUND

Groin hernia repair is one of the most common surgical procedures with approximately 20 million repairs performed annually in the world[1]. In Sweden, over 16.000 groin hernia operations are prospectively registered annually in the Swedish Hernia Register (SHR)[2]. Over the past 30 years, the SHR has achieved a national completeness and data validation level of 98%[3]. By creating a database of over 400.000 operations, the SHR has had a large impact on improving the quality of hernia surgery in Sweden as well as internationally[2].

There are mainly two important outcomes following a groin hernia repair that could impair the patient's quality of life; recurrence and chronic pain – both of them retained from the SHR and being main quality predictors for groin hernia repair in Sweden.

The life time risk of undergoing a repair for a groin hernia has been estimated to be 27% for men and 3% for women[4]. The prevalence of bilateral groin hernias among these has been reported up to 22%[5], while the prevalence of an asymptomatic contralateral groin hernia in patients with symptomatic unilateral groin hernia has been estimated to around 15%[6]. Around 30% of all asymptomatic groin hernias are predicted to become symptomatic and require a future repair[7].

Chronic pain following groin hernia repair has been described to have a rate somewhere in the range of 10-15 % after a groin hernia repair[8,9]. However, some studies have reported disturbing incidences up to 30-60 %, confirming that chronic pain is an unfortunate problem that impairs patients' quality of life[10,11].

The conditions of an asymptomatic groin hernia and an occult groin hernia may sometimes be exchangeable in the literature. However, it is important to distinguish the definitions from each other. The true incidence of occult hernias (defined as an asymptomatic hernia not detected by physical examination, but found intra-operatively) still remains uncertain and is suggested to be higher than originally expected[12]. In a recent systematic review by Dhanani et al., the incidence of an occult groin hernia was estimated to be 14.6% by the time of a laparoscopic repair[13]. Hence, the authors concluded that it was no indication for an immediate repair, since less than 10% of these occult hernias are likely to become symptomatic. On the other hand, Wu et al., suggested that simultaneous prophylactic repair of an asymptomatic contralateral hernia may prevent a repeat procedure in the future and without any significant side effects of patient recovery to daily life[7]. In a randomized controlled trial from 2006, O'Dwayer et al., demonstrated that a repair of an asymptomatic groin hernia has little effect on the rate of long-term chronic pain for patients[14]. Likewise, Park et al., have proposed that repairing an

asymptomatic contralateral groin hernias is associated with more benefits than risks for both the patient and for the society[5].

In contrast to the above-mentioned advantages of patients with bilateral groin hernias undergoing a simultaneous prophylactic repair of the asymptomatic contralateral groin hernia, some suggest that it is likely that there can be an increase in operation-time and prolonged immediate postoperative pain in these patients compared to those that only have their symptomatic unilateral groin hernia repaired[5]. Malouf et al., could confirm that the short-term postoperative pain was higher for bilateral repairs compared to unilateral repairs at 2 weeks postoperative control, but this difference resolved by 6 weeks after surgery[15]. Previous reports indicate no significant differences between unilateral hernia repairs compared to bilateral repairs considering length of hospital stay, postoperative complications or duration for returning to daily activity[5,16,17].

The European Hernia Society (EHS) guidelines recommend laparo-endoscopic repair for bilateral groin hernias if it is feasible and in agreement with the patients, but a routine's exploration of the contralateral groin is only suggested for the TAPP approach (transabdominal preperitoneal repair) and not for repairs performed through TEP (total extra-preperitoneal repair)[18]. EHS also state that although most patients with asymptomatic groin hernias will develop symptoms and need a future surgery, watchful waiting for an asymptomatic inguinal hernia is safe since the risk of hernia complications is low.[18]

An important withdrawal with previous studies is that it is not possible to predict whether the patients were operated laparoscopically because of bilateral symptoms, or if occult bilateral groin hernias were detected due to the laparoscopic approach.

The incidence and treatment of an asymptomatic contralateral groin hernia in patients with bilateral groin hernias have therefore been debated on in the past decades. The majority of bilateral hernias are operated laparoscopically and we are facing an increasing trend. Despite the high prevalence of bilateral groin hernias and asymptomatic contralateral groin hernias, there is currently no proper consensus on the timing of repair of the asymptomatic contralateral groin hernia.

Therefore, we aim with this large multicenter register- randomized controlled trial via a national highly validated Swedish register to investigate the outcomes of asymptomatic contralateral groin hernias in patients with bilateral groin hernias.

AIM and HYPOTHESIS

The aim is to investigate the differences in the outcome of chronic pain, reoperation, peri - and postoperative complications and patient satisfaction between laparo-endoscopic bilateral inguinal hernia repair with an asymptomatic contralateral groin hernia versus a laparo-endoscopic unilateral inguinal hernia repair without repairing the asymptomatic contralateral groin hernia in bilateral inguinal hernias in adults. Additionally, we aim to study the prevalence of future elective and emergency hernia repair of the unrepaired asymptomatic contralateral inguinal hernia.

The chronic pain, reoperation, peri - and postoperative complications and patient satisfaction is hypothesized to be equal between bilateral inguinal hernia repairs with an asymptomatic contralateral inguinal hernia compared to unilateral symptomatic inguinal hernia repairs.

STUDY OBJECTIVES

The exposure

Method of repair, containing two groups of allocation repairs;

Bilateral repair (exposure – intervention arm)
Unilateral repair (unexposure – standard arm)

Primary outcome

PROM - Patient-reported chronic pain postoperatively [Time Frame: 1 year after surgery]

To compare chronic pain 1 year after surgery between laparo-endoscopic bilateral inguinal hernia repair with an asymptomatic contralateral inguinal hernia (bilateral arm) versus a laparoscopic unilateral inguinal hernia repair (unilateral arm) without repairing the asymptomatic contralateral inguinal hernia in bilateral groin hernias in adults.

Secondary outcomes

To compare the two arms with regard to;

- **Risk of reoperation of the hernia repair** [Time Frame: within 2, 5 and 10 years]
- **Perioperative complications (safety)** [Time Frame: Intraoperatively]

- **Postoperative complications (safety)** [Time Frame: 30 days after surgery]
- **Rate of future elective hernia repair of the unrepaired asymptomatic contralateral inguinal hernia** [Time Frame: within 1, 2, 5 and 10 years]
- **Rate of future emergency hernia repair of the unrepaired asymptomatic contralateral inguinal hernia** [Time Frame: within 2 years]
- **Comparting <u>all women</u> in the study population to the men according to above outcomes** [Time Frame: different for outcomes]
- **Rate and characteristics of found femoral hernias in the total study population** [Time Frame: Intraoperatively]
- **Time of surgery** [Time Frame: Intraoperatively]
- **PROM - Patient satisfaction** [Time Frame: 1 after surgery]

METHOD

Trial design

The study is a register-based randomized controlled multicenter trial with patients that have bilateral inguinal hernias whereas one of the hernias (called the contralateral groin hernia) is asymptomatic. Patients are either randomized to a repair undergoing laparo-endoscopic bilateral inguinal hernia repair of both hernias or only a laparo-endoscopic unilateral inguinal hernia repair of the symptomatic inguinal hernia (Figure 1). The name of the trial is; the BILAP HERNIA Trial. Inclusion, randomization and follow-up will be conducted through a national register; the Swedish Hernia Register (SHR). At each participating unit, all patients who fulfill the inclusion criteria and none of the exclusion criteria will be invited in the study. After oral and written consent (see attachment A), the patients will be included in study. They will be given a question about pain to answer (Figure 2) before surgery and this will be recorded in their baseline characteristics. Patients are then randomized intra-operatively through the SHR to one of the allocation arms. During operation all patient and hernia characteristics are filled in prospectively by the operation-team in SHR according to the SHR register (see attachment B), forming the patients CRF (Clinical Research Form). 1 year after surgery, all participants will be sent out a PROM questionnaire according to the incorporated routine in the SHR (see attachment C) including questions addressing chronic pain and patient satisfaction.

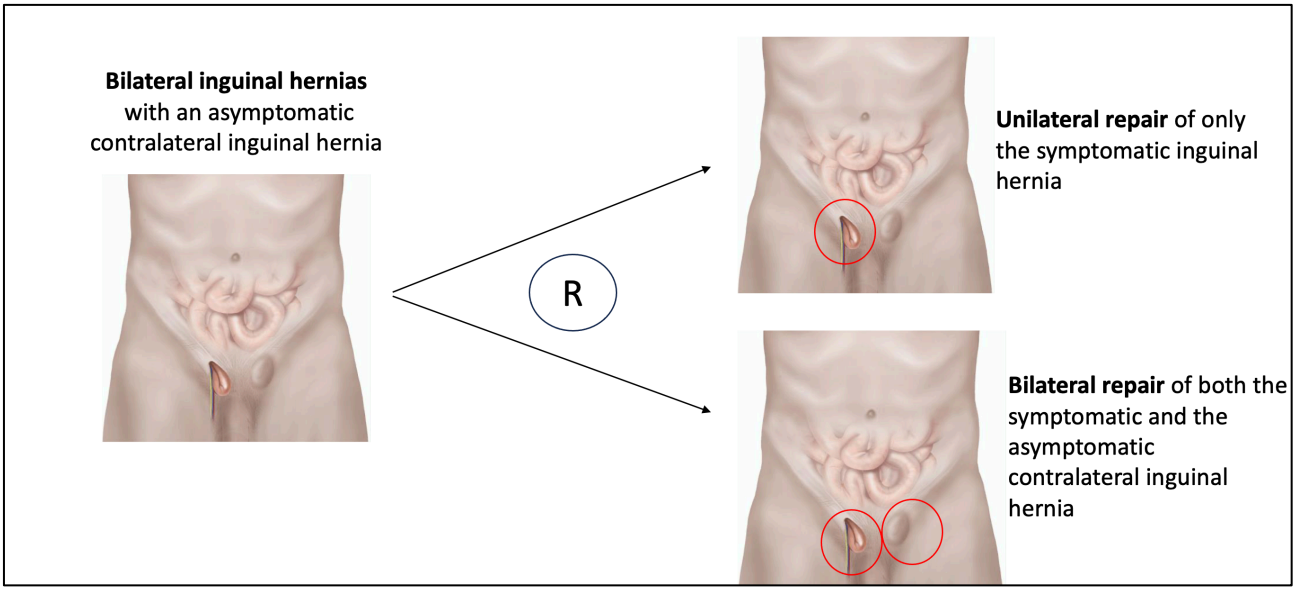

Figure 1. *Schematic illustration of the randomization and allocation arms*

Estimate the pain you experienced from your groin hernia prior to surgery.
1.No pain
2.Pain that could easily be ignored
3.Pain that could not be ignored but did not influence daily activities
4.Pain that could not be ignored, which affected concentration and performance of daily activities
5. Pain that inhibited most daily activities
6. Pain that required rest or bed rest
7. Pain so severe that you were forced to seek medical attention

Figure 2. *PROM addressing pain before surgery*

The Swedish Hernia Register

The Swedish Hernia Register (SHR) has near national coverage of surgical units across Sweden. More than 98% of all groin hernia operations from 90 surgical units performed in Sweden are registered in the SHR. It is a nationwide database of more than currently 400,000 groin hernia procedures[2]. Procedures are recorded prospectively by the surgeon during the operation and patients are identified using a personal identity-number, unique for each citizen in Sweden. The SHR is linked to the Swedish population registry to obtain accurate follow-ups. 10% of the aligned surgical units are checked independently each year. Validity of the SHR has been reported to be 98 % correct variables and a 97 % cover rate for procedures in the participating units, demonstrating that the SHR is a highly validated register[3].

PROM questionnaire

Between 2012 and 2018 a questionnaire assessing patient-reported outcome measures (PROMs) was sent out 1 year after surgery to all patients that had undergone a groin hernia repair from units participating in the SHR. The previous response rates have approximately been up to 72%. The distributed questions are extracted from the Inguinal Pain Questionnaire (IPQ)[19] and is a short-form questionnaire. A short-form questionnaire has shown to be exchangeable to the longer original version of IPQ[20]. This provides the unique opportunity to determine prospective collected patient-reported pain outcomes through a register. Studies reflecting the results of surgeons not specialized in hernia surgery are lacking today on assessing pain patients between different method of repairs, and especially on a large number of unselected hernias. This routine, by sending out PROM 1 year to all patients that has been undergone a groin hernia repair has now in 2025 again been incorporated in the SHR and will continue forward to be. The PROM questionnaire consists today of more questions (see attachment C). The population-based SHR offers a unique possibility to study this through a randomized controlled trial and send out the questionnaire again within a trial. Patients are followed from operation to re-operation, death or migration. Due to the personal identity-number, unique for each citizen in Sweden, patients can be followed until a reoperation for recurrence or pain and if a future elective or emergency repair has been done and registered within the framework of the SHR.

Definition of a symptomatic and asymptomatic inguinal hernia

A symptomatic inguinal hernia is defined as a clinical detectable reducible bulge (very small or large) in the groin above the inguinal ligament with symptoms of bulging, pain and discomfort.

An asymptomatic inguinal hernia is defined as a clinical detectable reducible bulge (very small or large) in the groin above the inguinal ligament where the patient has no symptoms of bulging, pain or discomfort. In some cases, the patients have not even noticed their asymptomatic hernia.

If preoperative imaging detects an inguinal hernia but the patient does not exhibit a clinically identifiable hernia during examination, this situation is not classified as an asymptomatic hernia. Preoperative imaging is not always reliable for diagnosing hernias, and clinical examination remains a critical component in assessment.

Selection of the study population

All adult patients referred for a groin hernia to outpatient clinical are eligible to the study and screened for inclusion. An unaware asymptomatic contralateral groin hernia might be present in the outpatient

clinic after examination by the surgeon. Patients randomized to only a unilateral hernia repair will be followed-up through the register to investigate both the risk of emergency hernia repair and the risk of a future elective repair of the asymptomatic not repaired hernia.

Inclusion criteria

- Elective laparo-endoscopic surgery of bilateral primary inguinal hernia in both men and women above and 18 years old, whereas one of the hernias is asymptomatic in a surgical center that perform > 50 laparo-endoscopic groin hernia repairs per year[22].

Exclusion criteria

- Recurrent groin hernias (earlier repair in the groin)
- Femoral hernias (both symptomatic and asymptomatic)
- Combined femoral groin hernias
- Detected femoral hernia during surgery (they will be recommended to be operated with a bilateral repair)
- Another operative procedure at the same time
- A history of open lower abdominal surgery (except appendectomy) like prostate surgery
- ASA fitness grade > 3
- Patients that cannot undergo general anesthesia
- Pregnancy
- Age < 18 years
- Infected wounds
- Emergency operation (incarcerated hernia)
- Inability to fill in questionnaires due to language barriers or condition as Alzheimer's

Femoral hernias

According to current guidelines, patients with femoral hernias (groin hernias below the inguinal ligament) are recommended for surgery whether they are symptomatic or asymptomatic[18]. This is due to literature reporting an increased rate of emergency repairs for femoral hernias. Femoral hernias are more common in women compared to men, whereas the most common groin hernias are still indirect inguinal hernias in both genders. It is not always easy to distinguish between a femoral and an inguinal hernia prior to surgery.

Patients with a known symptomatic or an asymptomatic femoral hernia prior surgery is an exclusion criterion in this trial. If a femoral hernia is found intra-operatively, the patient should be excluded, and it is recommended to repair the asymptomatic contralateral groin hernia, as there is an increased risk that this hernia is also femoral.

Preoperative and Perioperative process

Participants will be given a question to answer addressing the grade of pain in the groin hernia prior to surgery (Figure 2) before surgery and this will be recorded in their baseline characteristics. Participants are then randomized intra-operatively through the SHR to one of the allocation arms (see below). During operation all patient and hernia characteristics are filled in prospectively by the operation-team in SHR according to the SHR register (see attachment B), forming the patients CRF (Clinical Research Form).

Randomization process

Patients will be recruited to participate in the study during the clinical outpatient meeting with the surgeon if there is an indication for surgery. At each participating unit, all patients who fulfill the inclusion criteria and none of the exclusion criteria are invited in the study. After oral and written consent, the patients are included in the study. The randomization will take place intraoperatively after identifying the type of hernia at the symptomatic side. If no femoral hernia is found – randomization will take place. The patient is allocated to one of the arms. Each hospital will receive the same relationship (1:1, block randomization) between bilateral repair and unilateral repair.

Sample size estimation

The chronic pain rate 1 year after surgery in previous hand-full studies are ranging from 10-15% and up to 18% for women following groin hernia repair. We hypothesize that there is no significant difference in chronic pain rate 1 year after surgery between bilateral repair and unilateral repair as a non-inferiority trial. We assume a 12% chronic pain rate in both groups. If there is truly no difference between the standard and the intervention group for the binary primary outcome, then 2074 patients are required to be 80% sure that the upper limit of a one-sided 97.5% confidence interval (CI) (or equivalently a 95% two-sided CI) will exclude a difference in favor of the standard group of more than 4% (non-inferiority margin). In any case, the number of patients in each group must be increased by 10% to cover the expected patient drop off of the primary outcome of patient-reported chronic pain (this number has been decreased from earlier cohort studies of 30% to 10% due to that this trial will have reminders to the patients of the PROM questionnaire and an assumption of being included in a trial can increase the response rate). The estimated total amount of patients would be 2200. Approximately 16,000 groin

hernia repairs are performed annually in Sweden and approximately 3700 endo-laparoscopic repairs (25 surgical units of total 85) are being performed annually in surgical units that perform > 50 endo-laparoscopic groin hernia repairs per year (medium to high volume centra)[22]. The prevalence of an asymptomatic contralateral groin hernia in patients with symptomatic unilateral groin hernia has been estimated to be around 15%. This gives the trial approximately 555 patients to include annually and with some not meeting the inclusion criteria, we estimate an inclusion of approximately 450 patients annually. To include 2200 patients, the estimated inclusion period will be 4,8 years.

Multicenter trial

The study is a multicenter trial including several surgical units that can represents different regions in the Swedish nation. For authorship a substantive contribution to the work according to the ICMJE recommendations will be required. A minimum of 50 laparoscopic groin hernia repairs annually are required by the participating surgical unit to be included as a surgical unit in the trial.

Surgical technique – Laparo-endoscopic inguinal hernia repair

Both transabdominal preperitoneal (TAPP) and total extraperitoneal (TEP) repair are minimally invasive mesh techniques considered in this study. The surgeon can select the method they are most skilled in, but to qualify for participation, the surgical unit must perform a minimum of 50 procedures annually using either technique. In both approaches, it is essential to place a large-pore flat or preformed mesh (≥ 15x10 cm) in the preperitoneal space to cover all potential hernia orifices in the groin. No specific mesh or fixation method is mandated, though current evidence recommends atraumatic fixation (for example resorbable sutures or tackers or glue) when using lightweight mesh, particularly in bilateral hernias or large defects (>3 cm).

Both procedures require general anesthesia, with the patient positioned supine and legs elevated. Local anesthesia is applied prior to trocar insertion. The techniques differ primarily in how they access the preperitoneal space, but standardized dissection and meticulous parietalization are consistent in both. All connective tissue is dissected to expose Retzius and Bogros spaces while reducing direct, indirect, or femoral hernia content. For hernias, the sac is dissected from the transversalis fascia in Hesselbach's triangle for direct hernias or from the spermatic cord for indirect hernias, ensuring not to injure the genital branch of the genitofemoral nerve. Any lipomas in the cord or round ligament should be excised, and irreducible femoral hernias may require incision of the lacunar ligament. The peritoneum is reflected to expose the "inverted Y" structure of the inferior epigastric vessels and the vas deferens (or round ligament in females). An adequate space for the mesh is created by cutting the arcuate ligament laterally.

TAPP Procedure

TAPP accesses the abdominal cavity to place the mesh between the peritoneum and posterior abdominal wall via a peritoneal incision. Three trocars are insized in a supraumbilical position, spaced 6–8 cm apart. A 5 or 10 mm 30° laparoscopic camera is used, and pneumoperitoneum (10-15 mmHg) is established through open laparoscopy or CO2 insufflation via a Veress needle. A large peritoneal flap is prepared through an arcuate incision, facilitating adequate exposure of the myopectineal orifice for correct mesh positioning. The peritoneum is closed over the mesh using barbed sutures or glue, but not tackers of any kind. Pressure may be lowered before closure.

TEP Procedure

TEP is performed without entering the abdominal cavity, placing the mesh directly into the preperitoneal space. A subumbilical incision is made to access the anterior rectus sheath, which is then incised, allowing lateral retraction of the muscle to reveal the posterior sheath. A 10 mm 30° laparoscopic camera is introduced via a trocar to create the preperitoneal space using telescopic blunt dissection. Two additional 5 mm trocars are placed in the lower midline, ensuring adequate spacing. Fatty tissue in the preperitoneal space should remain in contact with the inguinal floor. The pubic symphysis is identified, and Cooper's ligament is bluntly dissected which will opens both the space of Retzius and the space of Bogros, allowing for mesh placement without covering the bladder. The peritoneum is mobilized to expose the triangle of doom adequately. A mesh large enough is placed to cover the inguinal and femoral areas.

Bilateral Repairs and Randomization

The randomization takes place intraoperatively after identifying the type of hernia at the symptomatic side. If no femoral hernia is found – randomization will take place. In randomized bilateral repairs (intervention group), the surgeon alternates sides after addressing the symptomatic side, standing on the opposite side of the hernia in both TAPP and TEP procedures. Dissection must be completed on both sides before inserting the mesh, with two overlapping meshes used for bilateral hernias. No trocar position changes are required, although additional trocars may be added in TAPP if necessary. The control group, receiving unilateral repairs, cannot undergo surgery on the contralateral side for occult hernias.

Postoperative outcomes and follow-up

The postoperative regime will be similar in the two allocation arms of repairs. Participants can be operated either as outpatients or inpatients due to the patients' comorbidity.

Participants will be followed-up within the regime of the Swedish Hernia Register (SHR). None of the participants will be routinely seen in the outpatient clinic for a clinical examination.

Chronic pain

At 1 year after surgery each participant, for each inguinal hernia repair (each groin), will be requested to fill in a PROM questionnaire within the framework of the SHR.

The question put to the participant that will address chronic pain will be item 2, extracted from the IPQ (Figure 2). The questionnaire will be sent out 1 year after the hernia repair to all participants in the trial via the SHR. Non-responders will have a reminder sent out again within 30 days. In the analysis, level 1-3 will be defined as no pain and level 4-7 as persistent significant chronic pain.

Estimate the worst pain you felt in the operated groin during this past week.
1.No pain
2.Pain that could easily be ignored
3.Pain that could not be ignored but did not influence daily activities
4.Pain that could not be ignored, which affected concentration and performance of daily activities
5. Pain that inhibited most daily activities
6. Pain that required rest or bed rest
7. Pain so severe that you were forced to seek medical attention

Figure 2. *PROM question addressing chronic pain 1 year after surgery, question number 2 from the IPQ.*

Reoperation

Reoperation within the framework of SHR can either be for recurrence or for pain.

The follow-up time for reoperation for recurrence will be within 2, 5 and 10 years after surgery.

Reoperation for recurrence will be defined as a new hernia repair due to recurrence or pain in the same groin where the previous index inguinal hernia repair had been performed and had been registered in

SHR. The time from the index repair to the reoperation will be calculated in days and described in median.

Perioperative and Postoperative complications

Different perioperative complications within the framework of the SHR will be investigated. Postoperative complications will be assessed 30 days after surgery and classified according to the Clavien-Dindo classification within the framework of the SHR 30 after surgery will be investigated to see differences between the groups (see attachment B).

Patient satisfaction

A question in the PROM questionnaire will assess patient's satisfaction with their groin hernia operation results. Selectable answers will be: 1) Yes, perfectible satisfied, 2) Yes, almost satisfied, 3) No, mainly not satisfied, 4) No, not at all satisfied. Patient dissatisfaction will be defined as a score > 2.

Emergency hernia repair

Emergency hernia repair within 2 years of the unrepaired asymptomatic contralateral inguinal hernia will be investigated via the SHR.

A future elective hernia repair

A future elective hernia repair of the asymptomatic contralateral inguinal hernia within 1, 2, 5 and 10 years will be investigated via the SHR.

Unrepaired asymptomatic inguinal hernia

The unilateral inguinal hernia repair participants will be registered in the SHR for their unilateral repair within the trial. They will be followed until reoperation of their previous symptomatic inguinal hernia or until a future elective or emergency repair of the asymptomatic hernia has been performed or until death. This is due to the unique personal number for each citizen in Sweden.

Trial subgroups

The trial will have one large main study population including all inguinal groin hernias in both men and women to be primary analyzed.

The trial will provide important clinical subgroups for analysis;

- All women with inguinal hernias – comparing the outcomes of chronic pain, reoperation, peri - and postoperative complications and patient satisfaction to all men
- All women with inguinal hernias - investigating the prevalence and the risk of future elective and emergency repair of the asymptomatic contralateral inguinal hernia compared to the men
- Rate and characteristics of found femoral hernias in the whole study population

Monitoring

The investigators at each unit are responsible to record and register patient's variables in the SHR. A special demonstration of the SHR within the Trial will be given to each unit and the involved surgeons by the principal investigator.

Statistical analysis

The statistical analysis and presentation of the data will be described in detail using program R in collaboration with statistical expertise. A statistical analysis plan (SAP) has been conducted. (see attachment D).

Study period

The study will start including trial participants year 2026/2027. Randomization of trial participants are estimated to be done within 5 years, 2030/20231. The follow-up of the primary outcome will be 1 year after surgery. The total follow-up of secondary outcomes will be 10 years after surgery.

ETHICAL CONSIDERATIONS

Guidelines for the recommended method of repair for patients with bilateral inguinal hernias with an asymptomatic contralateral inguinal hernia is still lacking today. Consequently, surgeons lack standard protocols in the clinical setting for these patients. The standard treatment is today a laparoscopic unilateral inguinal hernia repair with an unrepaired asymptomatic contralateral inguinal hernia. This is due to fear of the risk of chronic pain after surgery. However, in more high-volume laparoscopic surgical volume units both scenarios of bilateral and unilateral repair scan be accepted as standard treatments, however, with no scientific evidence. Watchful waiting of an asymptomatic inguinal hernia in men is considered accepted and safe and also recommended by the international guidelines if it align with the patient.

Conversely, one ethical withdrawal with this trial can be the treatment of women with bilateral inguinal hernias. According to current guidelines, women with a groin hernia are recommended for surgery whether they are symptomatic or asymptomatic or femoral or inguinal. This is due to literature reporting an increased rate of emergency repairs in women and for femoral hernias. Femoral hernias are more common in women compared to in men and are not always easy to distinguish from inguinal within the clinical examination. On the contrary, women report higher chronic pain rate after groin hernia surgery than men, up to 18%[21]. A chronic pain that is significant and influence daily life activities. Consequently, surgery on asymptomatic groin hernias in women can be debated due to the significant increased risk of chronic pain after surgery.

The trials study design is conducted in such way that an asymptomatic contralateral inguinal hernia (femoral hernias will be excluded and repaired) will be left out and unrepaired for watchful waiting in some women. In contrast, the trial will have a unique possibility to study watchful waiting and the risk of future elective and emergency repair in women with asymptomatic inguinal hernias within a randomized study population, which have never before been done.

PATIENT BENEFITS

One of the main aims of the establishment of The Swedish Hernia Register (SHR), was to study recurrence rates nationally and improve outcomes. Today, it is proven that both quality and cost-effectiveness of groin hernia repair have been improved in Sweden with a register participation. Guidelines for the recommended method of repair for patients with bilateral inguinal hernias with an asymptomatic contralateral inguinal hernia is still lacking today. Guidelines have stressed the need for reliable high-quality data from randomized trials to improve treatment recommendations for patients with contralateral asymptomatic hernias in bilateral inguinal hernias.

If the results of the trial will be in align with the hypothesis, all bilateral inguinal hernias with an asymptomatic contralateral hernia should undergo a simultaneous bilateral repair. An improvement of this approach may contribute a lot to the operated patients. This may mean that fewer patients will need to have a future elective inguinal hernia repair. It can also mean that the risk of having an emergency repair may be decreased. It also reduces patient anxiety of the asymptomatic inguinal hernia becoming symptomatic and emergency. A potential health-economic cost effectiveness is possibly, whereas patients only need one operation instead of two separates.

We can expect that the results from this register-based randomized controlled study will have a direct implication on the recommendations for hernia repair standards in patients with bilateral inguinal hernias and may contribute to set up more standard protocols in the clinical setting.

DATA-PROTOCOL PROTECTION

The investigators at each unit are responsible and will ensure the confidentiality of the clinical study protocol and data of the study. Each unit/surgeon will have a personal login and password to the SHR for registration. Only the principal investigators will have access to all registered information in SHR for the study population. Unidentified data will then be used in the final statistical analysis.

Revision Protocol History after Ethical approval

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