Single-Center Observational Study with Comparison of Endoscopic Extended-View Totally Extraperitoneal Prosthesis (eTEP) Versus Open Rives-Stoppa Repair as a Treatment of Midline Abdominal Wall Hernias with Rectus Diastasis

Study Protocol was composed according to the WHO data set [1] (version 1.3.1) and the SPIRIT 2013 statement [2].

0.1 Protocol additions

Version 2:

- Addition to participant flow (1.2.20)
- Completion of entry to ClinicalTrials.gov.

Version 3: Last updated December 26, 2022

- Addition of ClinicalTrials.gov ID (1.1)
- Addition to ‘actual sample size’ (1.2.14)
- Addition to ‘recruitment status’ (1.2.15)
- Addition of completion date (1.2.19)
- Addition to participant flow and flowchart (1.2.20)
- Additional registration to EHS-registry with addition to ‘baseline characteristics’ (1.2.20)
- Correction of ‘adverse events’ under 1.2.20 since participant previously denoted with an adverse event exhibited exclusion criteria and was not included
- Addition of ‘adverse events’ (1.2.20)
- Addition of ‘brief summary’ (1.2.20)
- Addition of ‘date of posting of results summaries’ (1.2.20)
- Addition to IPD sharing statement (1.2.21)
- Addition to ‘contributions’ (1.5)
- Addition to ‘statistical analysis’ (3.1.9)

1.1 Trial Registration

ClinicalTrials.gov:

- Date of Registration: June 24, 2022.
- NCT05446675

Secondary identifying number: EC/EH/220608-SK.

1.2 WHO Data Set

1.2.1 Monetary or Material Support

None.

1.2.2 Primary Sponsor

Department of Abdominal Surgery AZ Alma.

Ringlaan 15, 9900 Eeklo, Belgium.

1.2.3 Secondary Sponsors

None.

1.2.4 Contact for Public and Scientific Queries

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1.2.5 Public Title

Endoscopic eTEP versus Open Rives-Stoppa.

1.2.6 Scientific Title

Single-Center Observational Study with Comparison of Endoscopic Extended-View Totally Extraperitoneal Prosthesis (eTEP) Versus Open Rives-Stoppa Repair as a Treatment of Midline Abdominal Wall Hernias with Rectus Diastasis.

1.2.7 Countries of Recruitment

Belgium.

1.2.8 Health Conditions Studied

Midline abdominal wall hernias alongside rectus abdominis diastasis.

1.2.9 Interventions

Group 1 (eTEP): Patients who underwent an endoscopic repair of their midline abdominal wall hernias and rectus diastasis via the extended-view totally extraperitoneal prosthesis method within our center.

Group 2 (Rives-Stoppa, control group): Patients who underwent an open midline repair with sublay mesh according to the technique of Rives-Stoppa within our center.

1.2.10 Inclusion Criteria

Group 1 (eTEP):

- Patients who underwent an eTEP procedure in our center
- Preoperative existence of one or more midline abdominal wall hernias
- Preoperative existence of rectus abdominis diastasis

Group 2 (Rives-Stoppa, control group):

- Patients who underwent an open Rives-Stoppa (midline repair with sublay mesh) in our center

1.2.11 Exclusion Criteria

Group 1 (eTEP):

- Preoperative absence of midline abdominal wall hernias
- Preoperative absence of rectus abdominis diastasis
- Intraoperative performance of transverse abdominis release (TAR)
- Intraoperative inguinal hernia repair

Group 2 (Rives-Stoppa, control group):

- Intraoperative performance of transverse abdominis release (TAR)
- Intraoperative performance of anterior component separation
- Intraoperative inguinal hernia repair

1.2.12 Study Type

Single-center, observational study.

Non-randomized allocation:

- Group 1 (eTEP): First 30 patients who meet the inclusion criteria and do not exhibit any of the exclusion criteria will be investigated. The option for endoscopic eTEP repair, if feasible, is given preoperatively as a standard for the treatment of symptomatic midline abdominal wall hernias with concomitant rectus abdominis diastasis as an alternative to open Rives-Stoppa mesh repair. The modality of operative treatment is made in cooperation with the patient.

- Group 2 (Rives-Stoppa, control): Thirty patients will be selected out of all patients who underwent an open Rives-Stoppa (midline repair with sublay mesh) in our center and who do not meet any of the exclusion criteria. Patient selection will consist of matching to patients in group 1 according to gender and age (e.g. a male patient in group 1 will be matched to a male patient (group 2) out of our records

who underwent an open Rives-Stoppa repair and whose age most closely resembles the age of the matched patient in group 1).

Masking: None.

Assignment: Two-group, parallel.

Purpose: Comparing two routinely used interventions for the treatment of midline abdominal wall hernias with rectus abdominis diastasis.

1.2.13 Date of First Enrollment

June 9, 2022.

1.2.14 Sample Size

Planned:

- Group 1 (eTEP): 30 participants
- Group 2 (Rives-Stoppa, control): 30 participants

Actual:

- Group 1 (eTEP): 30 participants
- Group 2 (Rives-Stoppa, control): 30 participants

1.2.15 Recruitment Status

Completed.

1.2.16 Primary Outcomes

- Outcome name: Length of hospital stay
  Method of measurement: Time (days) spent within the hospital
  Timepoint: Start at day of operation (day zero) until day of discharge

- Outcome name: Postoperative pain management
  Method of measurement: Modality (type, generic name), duration (days), dosage (grams or milligrams) and frequency (times per day) of analgesics administration
  Timepoint: During hospital stay

1.2.17 Secondary Outcomes

- Outcome name: Intraoperative complications
  Method of measurement: Adverse event occurrence
  Timepoint: During surgery

- Outcome name: Postoperative complications
  Method of measurement: Adverse event occurrence by readmission
  Timepoint: After discharge until 30 days postoperative

1.2.18 Ethics Review

Ethics approval was granted on June 9, 2022, by the “Commissie voor Ethiek” at AZ Alma, after deliberation at their meeting on June 8, 2022.

1.2.19 Completion Date

Planned: September 30, 2022.

Actual: December 23, 2022.

1.2.20 Summary of Results

Date of posting of results summaries: December 26, 2022 (within study protocol).

Date of the first journal publication of results: Not yet achieved.

URL: Not (yet) applicable.

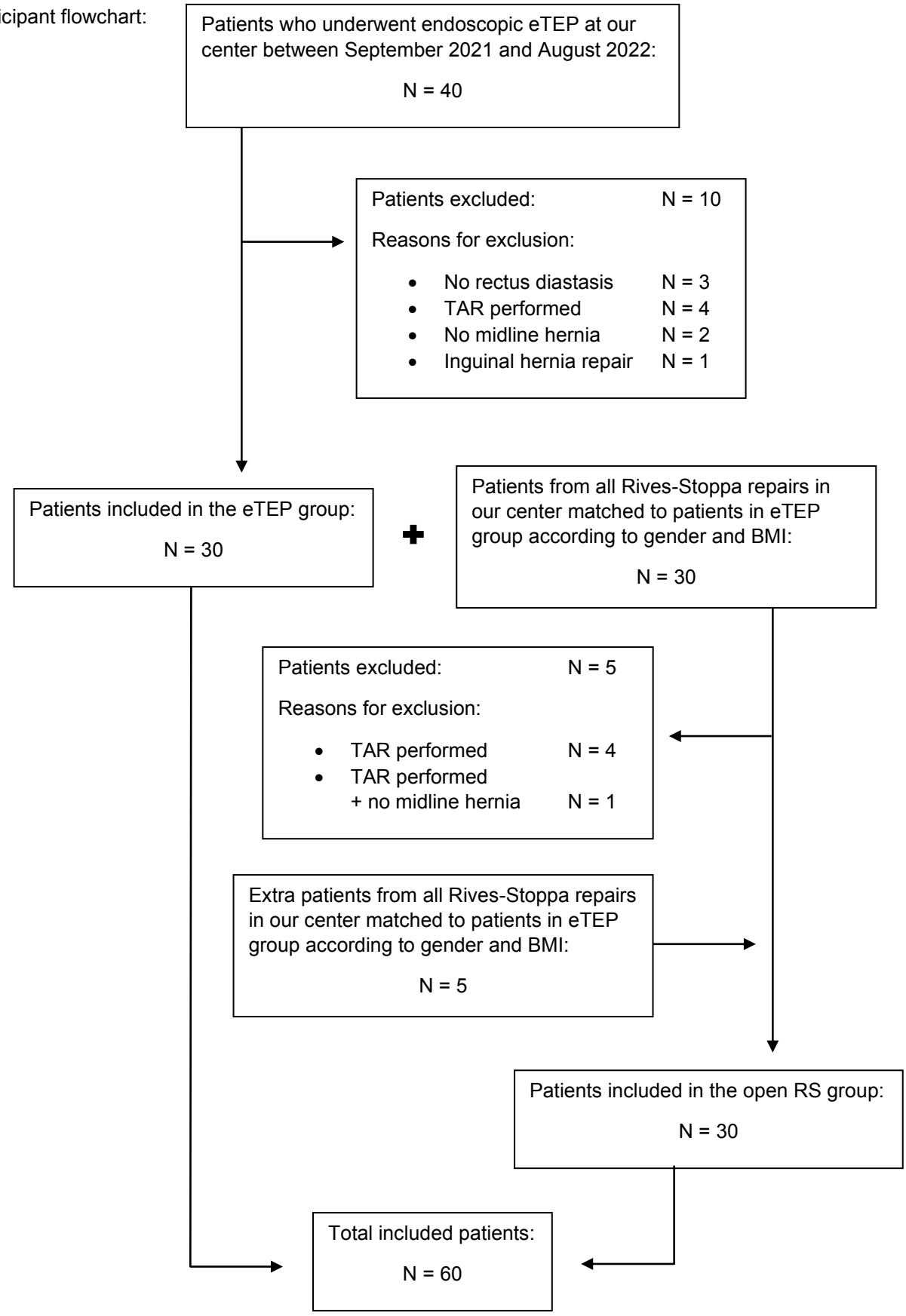
Baseline characteristics:

- Group 1 (eTEP): EHS Registry: BEGZ, BEHA, BEHB, BEJR, BEJS, BEJT, BEJW, BEJX, BEJZ, BEKA, BEKB, BEKC, BEKG, BEKH, BEKI, BEKJ, BEKK, BEKL, BEKM, BELE, BELF, BELG, BELH, BELI, BELJ, BELK, BELL, BEOD, BETJ, BETK.
- Group 2 (Open RS): EHS Registry: BELN, BELO, BELQ, BELR, BELS, BELT, BELU, BELV, BELW, BELY, BEOF, BEOH, BEOO, BEPV, BEPX, BEPY, BEPZ, BEQA, BEQF, BEQG, BEQJ, BEQK, BEQQ, BEQR, BEQS, BEQT, BEQV, BEQX, BETN, BETO.

Participant flow (see also participant flowchart on next page):

Date	Group 1	Group 2
June 9, 2022	23 participants	23 participants
June 13, 2022	24 participants	24 participants
June 17, 2022	25 participants	25 participants
June 20, 2022	26 participants	26 participants
June 21, 2022	27 participants	27 participants
July 11, 2022	28 participants	28 participants
August 30, 2022	30 participants	30 participants

Participant flowchart:



Adverse events:

- Three conversions were needed in group 1 (eTEP) because no adequate visualization could be achieved (1 participant) or because the diastasis was deemed to large to be appropriately closed endoscopically (2 participants)
- Observed complicationa according to the Clavien-Dindo (CD) classification [3]:
  During hospital stay in the eTEP group: 1x CD I, 12x CD II.
  During hospital stay in the Open RS group: 4x CD I, 10x CD II, 4x CD IIIb.
  After discharge until 30 days in the eTEP group: 5x CD I, 1x CD II, 2x CD IIIa, 1x CD IIIb.
  After discharge until 30 days in the Open RS group: 5x CD I, 1x CD II, 5x CD IIIa, 4x CD IIIb.

Outcome measures: See brief summary.

URL protocol files: Not applicable.

Brief summary:

- Median length of hospital stay was longer in the open RS group.
- Median duration of patient-controlled analgesia was longer in the open RS group.
- Switch to only oral analgesics took longer in the open RS group.
- No significant difference in ‘comparable parameter’* for postoperatively administered analgesics irrespective of PCA between both groups.
- No significant difference between the presence of prescription opioids at discharge.
- Median duration of surgery (skin-to-skin time) was significantly shorter in the open RS group.
- Need for drainage (postoperative drain inserted during primary surgery) was significantly greater in the open RS group.
- No early recurrences were found in both groups (postoperative consultation at approximately one month after surgery).
- Bulging of the abdominal midline was seen in 11 participants in the eTEP group and was not seen in the open RS group, this difference was statistically significant.

  *Comparable parameter: Types of analgesics were divided into three categories. Category 1 contained only paracetamol, category 2 contained all non-steroidal anti-inflammatory drugs, and category 3 consisted of all opioids. A combination of active substances (in one analgesic) of which at least one was an opioid was seen as category 3. For each participant the absolute amount of analgesics in each category was calculated between postoperative day one and the day before discharge, this amount was divided by the amount of days between postoperative day one and the day before discharge.

1.2.21 IPD Sharing Statement

IPD will be shared via the online EHS registry with contents adhering to their format. Accessible to all EHS members for all types of analyses. Currently shared: BEGZ, BEHA, BEHB, BEJR, BEJS, BEJT, BEJW, BEJX, BEJZ, BEKA, BEKB, BEKC, BEKG, BEKH, BEKI, BEKJ, BEKK, BEKL, BEKM, BELE, BELF, BELG, BELH, BELI, BELJ, BELK, BELL, BEOD, BETJ, BETK, BELN, BELO, BELQ, BELR, BELS, BELT, BELU, BELV, BELW, BELY, BEOF, BEOH, BEOO, BEPV, BEPX, BEPY, BEPZ, BEQA, BEQF, BEQG, BEQJ, BEQK, BEQQ, BEQR, BEQS, BEQT, BEQV, BEQX, BETN, BETO.

1.3 Protocol Version

Protocol version 3, December 26, 2022.

1.4 Funding

No finincial, material or other support.

1.5 Roles and Responsibilities

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Contributions:

All contributors contributed to the study conception and design. Material preparation, data collection and analysis were performed by contributor 1. The study protocol and first draft of the manuscript were written by contributor 1 and all authors commented on previous versions of the study protocol and manuscript. Statistical analysis was performed by contributor 1 after consultation with a biostatistician. All contributors read and approved the final study protocol and manuscript.

2.1 Introduction

2.1.1 Background and Rationale:

Extended view totally extraperitoneal prosthesis (eTEP) repair is a fairly new, up-and-coming technique as a treatment option for ventral abdominal wall hernias. The endoscopic eTEP approach has been proven to be a feasible approach [4, 5]. Our center recently started offering this treatment option from September 7, 2021 (first performance of the eTEP surgery within our center) onwards as a minimally invasive alternative to an open Rives-Stoppa [6] repair. A quick search revealed some comparisons of eTEP with IPOM [7], or comparisons between robotic and endoscopic eTEP [8], but little or no information could be found about comparisons between endoscopic (non-robot-assisted) eTEP and open Rives-Stoppa repair. Since the endoscopic eTEP repair and the open Rives-Stoppa repair both consist of a retromuscular mesh placement, and the endoscopic eTEP procedure is offered as a minimally invasive alternative to an open Rives-Stoppa repair in our center, an objective comparison between the two of them seemed logical.

2.1.2 Objectives:

To compare the outcomes of endoscopic eTEP repair versus open Rives-Stoppa repair in terms of length of hospital stay, postoperative pain management and complications.

2.1.3 Trial Design:

Partially retrospective, partially prospective, two-group, parallel, observational, superiority cohort study with an allocation ratio of 1:1.

3.1 Methods: Participants, Interventions and Outcomes

3.1.1 Study setting

AZ Alma Eeklo, general hospital.

Country of data collection: Belgium.

3.1.2 Eligibility criteria

Inclusion and exclusion criteria for participants are listed under 1.2.10 and 1.2.11 respectively. AZ Alma Eeklo is the only eligible center. The eligible surgeons are those listed under 1.5 as contributor 2, contributor 3 and contributor 4.

3.1.3 Interventions

Explained under 1.2.9 and elaborated under 1.2.10, 1.2.11 and 1.2.12. All procedures were performed or will be performed by one of three surgeons listed under 1.5 as contributor 2, contributor 3 and contributor 4.

3.1.4 Outcomes

Primary and secondary outcomes are listed under 1.2.16 and 1.2.17 respectively.

3.1.5 Participant timeline

See “Participant flow” under 1.2.20.

3.1.6 Sample size

Explained under 1.2.14.

3.1.7 Recruitment

No specific recruitment measures are undertaken. Participants are recruited retrospectively post-surgery, or, if possible at consultation when they present with eligible pathology and inclusion criteria. No difference to normal standard of care is made. From September 2021 onwards, the eTEP procedure was offered as an alternative to open Rives-Stoppa mesh repair for eligible participants.

3.1.8 Methods: Assignment of interventions

Not applicable (not a controlled trial). No sequence generation, allocation concealment or blinding were applied. Matching of the control group is elaborated under 1.2.12. Participants are enrolled by one of three surgeons listed under 1.5 as contributor 2, 3 and 4. Matching of participants and (retrospective) creation of the control (Rives-Stoppa) group is done by contributor 1.

3.1.9 Methods: Data collection, management, and analysis

Data collection is done by reviewing the electronic medical records of participants. No additional tests or interventions are undertaken other to those that are considered as standard of care. Collected data can be found in the EHS-registry as mentioned under 1.2.20 and 1.2.21. Additional data (if applicable) will be supplied within the final report. All relevant data regarding the outcome measures explained under 1.2.16 and 1.2.17 will be collected for all enrolled participants.

Uncoded data is entered and stored to files only accessible to members of the primary sponsor (1.2.2). Data quality will be regularly checked by contributor 1.

A biostatistician was consulted for advice regarding statistical analysis. Statistical analysis was performed by contributor 1. JASP [9] was used for the majority of statistical analysis, Vassarstats [10] was used to calculate Fisher’s exact tests on 3 x 2 contingency tables, XLSTAT [11] was used to create Kaplan-Meier curves.

3.1.10 Methods: Data monitoring

A specific data monitoring committee other than the primary sponsor was deemed irrelevant given the observational nature of the study. Interim results will only be available to the primary sponsor. No specific stopping guidelines are in effect.

Adverse events are part of the secondary outcomes (1.2.17) and will be given within the final report. Unintended events will also be reported within the final manuscript.

Auditing of intended trial conduct was assessed at ethics review during the meeting of “Commissie voor Ethiek” at AZ Alma on June 8, 2022. No further auditing is intended.

4.1 Ethics and Dissemination

4.1.1 Research ethics approval

As stated under 1.2.18, ethics approval was granted on June 9, 2022, by the “Commissie voor Ethiek” at AZ Alma, after deliberation at their meeting on June 8, 2022.

4.1.2 Protocol amendments

Amendments and complements are stated at the top of the protocol. Important protocol modifications (if applicable) will be separately communicated with all relevant parties. Final version of the protocol will be supplied to the journal at submission.

4.1.3 Consent or assent

Informed consent of all participants is obtained prior to surgery by one of the contributors listed under 1.5, and stored within the electronic medical record of the respective participant. Additional consent forms will be sent to all enrolled participants after achievement of final sample size.

4.1.4 Confidentiality

Uncoded data will only be accessible by the primary sponsor (1.2.2), which consists of the team of attending physicians. Only anonymised and relevant data will be available through the final manuscript and the EHS-registry as stated under 1.2.21. Data collection, management and monitoring are explained under 3.1.9 and 3.1.10.

4.1.5 Declaration of interest

All contributors declare that they have no competing interests. No funding was acquired.

4.1.6 Access to data

Final study dataset will be available to the primary sponsor and relevant data will be supplied within the final manuscript. Anonymised relevant data is also available at the EHS-registry (see 1.2.20, 1.2.21 and 4.1.4). Access is not limited to any contractual agreements.

4.1.7 Ancillary and post-trial care

Because both studied interventions are part of the standard of care, no specific additional care is foreseen or deemed applicable.

4.1.8 Dissemination policy

The primary sponsor and investigators/contributors plan to publish the results to a medical journal (title to be discussed). Data will also be available at the EHS-registry (see 1.2.20, 1.2.21, 4.1.4 and 4.1.6).

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by contributor 1 (see 1.5). The first draft of the manuscript will be written by contributor 1 and all authors/contributors will comment on previous versions of the manuscript. All authors/contributors will read and approve of the final manuscript. No intended use of professional writers.

If allowed by the accepting journal, the study protocol will be made publicly available. Participant level dataset will be available (anonymized) at the EHS-registry as stated above. Statistical code is discussed under 3.1.9.

5.1 Appendices

5.1.1 Informed consent

Translated version of the informed consent (original in Dutch) given to the participants prior to surgery.

Point 6 is of particular interest to the conducted study.

As a patient, you have the right to information about your condition and recommended surgical, medical and diagnostic procedures. You can only make a decision about undergoing a procedure/surgery if you have been sufficiently informed about the cost of the treatment, the purpose and risks of the treatment, the risks of not treating or delaying treatment, other treatment options and diagnostic investigations. This information is not intended to alarm you. The intention is to provide you with sufficient information, so that you can make a good decision whether or not you want to undergo the procedure/operation. You have the right to receive additional explanations from your doctor if you do not fully understand the information.

1. The undersigned clearly declares that they do / do not (note 1) grant permission to the following surgery/procedure: (eTEP or open Rives-Stoppa). As a result, an admission and/or ambulatory procedure is foreseen at AZ Alma from / on: (date of admission / surgery).

2. On (date of consultation prior to surgery) the doctor did / did not (note 1) give precise information about my state of health and about the diagnosis (midline abdominal wall hernia with rectus diastasis / other reason for Rives-Stoppa repair) that deemes this intervention/procedure necessary. They have explained to me the possible evolution if the above procedure is not followed, in simple and understandable terms. They also gave me information regarding other treatments/investigations, if any, with their pros and cons. They also explained to me the usefulness and effectiveness of the proposed treatment.

3. The doctor did / didn't (note 1) clearly describe the nature and the intervention/procedure itself, any inconveniences that may result, as well as the risks and possible immediate and late complications. I have received oral and/or written explanations in this regard. I realize that most diagnostic, surgical or medical procedures can lead to inflammation, bleeding, blood clots (thrombosis) and allergic reactions. With regard to the planned procedure, I was also informed about other possible risks, in particular: (expanding care if necessary and acting on perioperative findings, possibility of conversion if eTEP). I also understand that medical clinical practice is not

an exact science, that a list of possible complications can never be exhaustive and that no commitment/agreement can be made about the final outcome of the intervention/procedure.

4. I was / wasn't (note 1) informed that during the intervention/procedure/admission, in case of unforeseen circumstances, the doctor may be forced to extend the intervention/procedure with additional treatments, different from those originally foreseen. In these circumstances, I authorize the physician to take any action he deems absolutely necessary to maintain or restore my state of health. (= DNR 0: apply full resuscitation procedure, as well as maximum therapeutic support)
5. I do / do not (note 1) give permission to receive blood products if necessary. An information brochure is available for the patient (note 2).

6. I do / do not (note 1) give permission to use all visual material, photos, body material and personal data that are taken or collected from me as a result of the intervention/procedure, and that are unrecognizable, for educational purposes, scientific research or processing in objective medical-scientific information.

7. I have / have not (note 1) been informed of an estimate of the financial costs associated with this type of treatment/procedure, in regard to to my personal requirements. I myself will inform about the extent of the intervention of my hospitalization insurance.

8. I do / do not (note 1) give permission to the doctor mentioned below to perform the intervention or procedure in collaboration with a doctor or doctor-specialist in training of his/her choice.

9. I did / didn't (note 1) have the opportunity to ask questions and the doctor answered them satisfactorily. I have understood the answers correctly.

10. I declare that I have honestly informed the physician of my pre-existing health condition.

I do / do not (note 1) give my consent for the abovementioned treatment/procedure to be carried out.

Date: (date of signature).

Signature of the patient or his legal representative, to be stated “read and approved”.

Doctor's signature and stamp.

Notes to the informed consent form:

1. Cross out which one does not fit.
2. If you do not agree with point 5 (blood transfusion), please complete the discharge form for patients who refuse a blood administration.
3. For the storage of cells and tissue you must give permission on a separate form.
4. The following appendices (description) are part of this document: (description of appendices if applicable).

5.1.2 Biological specimens

Not applicable.

References

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