

STUDY PROTOCOL

A Prospective Endoscopic Study of the Presence, Type and Size of Corona Mortis in 300 Patients Undergoing Total Extraperitoneal (TEP) Inguinal Hernia Repair Procedures

Official Title

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Sponsor	Sofamed University Hospital
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Study site	Department of Surgery, Sofamed University Hospital, Sofia, Bulgaria

Document provenance: This English protocol consolidates the original Bulgarian and English study protocol materials for retrospective registration and results disclosure. The document contains the study objectives, design and methods only. It does not include study results, a post hoc statistical analysis plan, or an informed consent form.

CONFIDENTIALITY

This protocol contains no participant-identifiable information. Uploaded study documents may be made publicly available.

1. Document Control

Version	Date	Status	Description
1.0	17 July 2026	Current	Consolidated English protocol prepared from the original study documents for ClinicalTrials.gov submission.

2. Protocol Synopsis

Study title	A Prospective Endoscopic Study of the Presence, Type and Size of Corona Mortis in 300 Patients Undergoing Total Extraperitoneal (TEP) Inguinal Hernia Repair Procedures
Study type	Prospective, single-center, observational, descriptive study
Observational model	One cohort (case-only)
Study population	Adults aged 18 to 90 years with primary or recurrent unilateral or bilateral inguinal hernia who undergo TEP repair
Planned enrollment	300 participants
Study setting	Department of Surgery, Sofiamed University Hospital, Sofia, Bulgaria
Study period	February 2020 to June 2021
Primary objective	To determine the presence, anatomical type and vessel diameter of corona mortis during TEP inguinal hernia repair
Observation units	Participant, examined hemipelvis and individual identified vessel, as applicable to the outcome
Study-specific intervention	None. The TEP procedure is clinically indicated and is not assigned by the observational protocol.
Biospecimens	None collected or retained

3. Background and Rationale

Corona mortis is an arterial and/or venous vascular connection between the obturator vascular system and the external iliac vascular system, most commonly involving the inferior epigastric vessels. It courses along the posterior aspect of the superior pubic ramus. Injury to this vascular variant may result in substantial hemorrhage during pelvic trauma or surgery.

The anatomy is clinically relevant to orthopedic, urologic, gynecologic, oncologic and general surgical procedures, including minimally invasive inguinal hernia repair. Surgeons operating in the retropubic and preperitoneal spaces should recognize the potential location and configuration of these vessels.

Much of the available anatomical information has historically been derived from cadaveric studies. Direct in vivo observation during total extraperitoneal inguinal hernia repair provides an opportunity to document the presence, type and caliber of corona mortis under operative conditions without introducing an additional invasive procedure.

4. Study Objectives

4.1 Primary objective

- To describe the presence, anatomical type and vessel diameter of corona mortis in patients undergoing TEP inguinal hernia repair.

4.2 Additional objective

- To provide in vivo descriptive information on the preperitoneal vascular anatomy of the inguinal and retropubic regions.

5. Study Design

This is a prospective, single-center, observational and descriptive study. All participants form one observational cohort.

The surgical indication and selection of TEP repair are determined as part of routine clinical care. The protocol does not assign participants to a treatment group, does not compare therapeutic interventions and does not alter the planned operation.

TEP repair may be performed using routine three-port access with one or three skin incisions according to the operating surgeon's standard technique. The access configuration is not assigned by the study protocol.

The relevant anatomical structures are evaluated during the standard preperitoneal dissection. No additional dissection is required solely for research purposes beyond what is considered appropriate and safe during the operation.

6. Study Population

6.1 Target population

Adult patients with a diagnosed primary or recurrent unilateral or bilateral inguinal hernia who are scheduled to undergo total extraperitoneal inguinal hernia repair at Sofiamed University Hospital.

6.2 Planned sample size

The planned enrollment is 300 participants. The number of examined hemipelvis depends on hernia laterality: one hemipelvis is examined during unilateral repair and both hemipelvis are examined during bilateral repair.

6.3 Inclusion criteria

- Age 18 to 90 years, inclusive.
- Diagnosed primary or recurrent unilateral or bilateral inguinal hernia.
- Planned total extraperitoneal inguinal hernia repair.

6.4 Exclusion criteria

- Age younger than 18 years or older than 90 years.
- The patient elects or requires a surgical approach other than TEP before the study-specific anatomical observation is completed.

6.5 Healthy volunteers

Healthy volunteers are not eligible.

7. Study Procedures

7.1 Enrollment and baseline information

Eligibility is assessed before surgery. Baseline information includes age, sex, hernia laterality and whether the hernia is primary or recurrent.

The participant's clinical management is not modified by participation in the observational study.

7.2 Intraoperative anatomical assessment

1. During standard preperitoneal dissection, the retropubic vascular anatomy is inspected in each surgically exposed hemipelvis.
2. For unilateral hernia repair, one hemipelvis is evaluated. For bilateral hernia repair, both hemipelves are evaluated.
3. The presence or absence of corona mortis is recorded for each examined hemipelvis.
4. When corona mortis is present, its anatomical type is classified as arterial, venous, or combined arterial and venous.
5. The operative finding is documented photographically when technically feasible and clinically appropriate.
6. The diameter of each identified vessel is measured in millimeters using a sterile ruler introduced through a 10-mm trocar.
7. When more than one vessel is identified in the same hemipelvis, each vessel is documented and measured separately.

7.3 End of study observation

Study-specific observation ends at completion of the TEP procedure. The protocol does not mandate additional postoperative visits, imaging, laboratory testing or long-term follow-up for the anatomical outcomes.

8. Outcome Measures

8.1 Presence of corona mortis

Definition: Presence or absence of corona mortis in each examined hemipelvis. One hemipelvis is assessed in unilateral repair and both hemipelves are assessed in bilateral repair.

Time frame: Intraoperative, during retropubic dissection in the TEP procedure.

8.2 Type of corona mortis

Definition: Anatomical classification of each corona mortis-positive hemipelvis as arterial, venous, or combined arterial and venous.

Time frame: Intraoperative, during retropubic dissection in the TEP procedure.

8.3 Diameter of corona mortis vessels

Definition: Diameter in millimeters of each identified arterial and/or venous corona mortis vessel, measured with a sterile ruler introduced through a 10-mm trocar.

Time frame: Intraoperative, during retropubic dissection in the TEP procedure.

8.4 Secondary outcomes

No prespecified secondary outcome measures are included in this protocol.

9. Safety and Adverse Event Information

This is a non-interventional anatomical observation conducted during a clinically indicated surgical procedure. No study-specific treatment is administered.

Adverse event information for the study is limited to events identifiable in the operative record during the period from the start to the end of the TEP procedure. The protocol does not include systematic postoperative adverse event surveillance.

All-cause mortality is assessed during the same intraoperative observation period.

Clinical complications are managed according to the hospital's standard surgical and anesthetic practice and are not managed by a separate research intervention.

10. Data Collection and Management

Study data are recorded in a structured study dataset using a unique study code. The dataset includes participant-level demographic and hernia information, hemipelvis-level anatomical findings and vessel-level measurements when corona mortis is present.

Intraoperative images are stored in accordance with institutional clinical and research data procedures. Public study reports and uploaded documents must not contain participant names, medical record numbers, dates of birth, facial images or other direct identifiers.

Access to source records and the study dataset is restricted to authorized members of the study team. Data are retained according to applicable institutional and legal requirements.

Any correction to the study dataset should be traceable to the source documentation and should preserve the integrity of the original record.

11. Quality Assurance

Anatomical findings are documented at the time of surgery. Measurements are performed with a ruler visible in the operative field to support consistent recording in millimeters.

Data completeness and internal consistency are reviewed before finalization of the study dataset. Ambiguous measurements are checked against the original operative documentation and image, when available.

12. Ethical Considerations

The protocol requires compliance with the institutional ethics and human-subject protection requirements applicable to prospective observational research.

Participation does not determine the indication for surgery or the selection of TEP repair. The study-related activity consists of documenting anatomy visible during the clinically indicated operation.

The consent process must cover participation in the observational study and the recording and research use of intraoperative anatomical images, as required by the responsible institution.

The rights, safety and clinical interests of the participant take precedence over completion of any study observation or measurement.

13. Confidentiality and Data Protection

Confidentiality is maintained by using coded study data and by excluding direct participant identifiers from study analyses, publications and public registry documents. Data processing is performed in accordance with applicable institutional and legal data-protection requirements.

14. Dissemination of Results

Study findings may be submitted to ClinicalTrials.gov and disseminated through scientific presentations and peer-reviewed publications. Reports will present aggregate data and will not disclose participant-identifiable information.

15. Protocol Deviations and Amendments

Substantive deviations from the protocol and formal amendments are documented by the responsible study team. Where required, amendments are submitted to the relevant institutional review body. The public registry record should be updated when protocol information changes.

End of protocol