

STATISTICAL ANALYSIS PLAN

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

ClinicalTrials.gov identifier	NCT04303442
Protocol identifier	CMOR-TEP-300
Document type	Statistical Analysis Plan (only)
Version	1.0
Document date	17 July 2026
Timing status	Post-completion; not prospectively prespecified
Sponsor	Sofiamed University Hospital
Study site	Department of Surgery, Sofiamed University Hospital, Sofia, Bulgaria

Transparency statement: This statistical analysis plan was prepared after completion of data collection and was not available before the study was conducted. The three core anatomical outcomes - presence, type and vessel diameter of corona mortis - were specified in the original study protocol. The detailed statistical procedures and exploratory comparisons in this document are post-completion analyses prepared for transparent registry reporting and scientific dissemination. No study results are included in this document.

PUBLIC DOCUMENT

This document contains no participant-identifiable information and may be posted publicly on ClinicalTrials.gov.

1. Document Control

Version	Date	Status	Description
1.0	17 July 2026	Current	Initial post-completion SAP prepared for ClinicalTrials.gov results submission.

2. Study and Analysis Synopsis

Study design	Prospective, single-center, observational, descriptive study with one cohort.
Target enrollment	300 participants undergoing clinically indicated TEP inguinal hernia repair.
Core outcomes	Presence of corona mortis, anatomical type of corona mortis, and diameter of identified vessels.
Observation levels	Participant level, hemipelvis level, and individual vessel level, depending on the analysis.
Primary analysis approach	Descriptive summary of the three protocol-defined anatomical outcomes.
Exploratory analyses	Associations with sex, age, side, unilateral versus bilateral hernia, vessel type and vessel-size category.
Significance level	Two-sided alpha = 0.05 for exploratory hypothesis tests.
Missing data	No imputation; available-case analysis with outcome-specific denominators.
Multiplicity	No formal multiplicity adjustment; inferential p-values are exploratory and nominal.

3. Timing and Prespecification Status

The original protocol prospectively defined the evaluation of the presence, anatomical type and size of corona mortis during TEP repair.

This SAP was written after the study had been completed. It must not be interpreted as evidence that the detailed statistical tests, subgroup comparisons, data-handling rules or reporting conventions below were prospectively prespecified.

The core outcome analyses are protocol-aligned. Additional comparative and association analyses are exploratory and are identified as such in this document and in any resulting publication or registry interpretation.

4. Objectives and Outcome Variables

4.1 Primary descriptive objectives

- To determine the presence or absence of corona mortis in each examined hemipelvis.
- To classify corona mortis-positive hemipelves as arterial, venous, or combined arterial and venous.
- To describe the diameter in millimeters of each identified arterial and/or venous corona mortis vessel.

4.2 Exploratory objectives

- To explore whether the presence of corona mortis differs by participant sex, age, examined side, or unilateral versus bilateral inguinal hernia.
- To explore within-participant right-left concordance among participants undergoing bilateral TEP repair.
- To compare vessel diameter by vessel type, side, sex, age group and hernia laterality.
- To explore the relationship between participant age and the diameter of the dominant corona mortis vessel.

5. Data Structure and Units of Analysis

The dataset is hierarchical. A participant may contribute one examined hemipelvis for unilateral repair or two examined hemipelves for bilateral repair. A corona mortis-positive hemipelvis may contain one or more individually measured vessels.

Analysis unit	Variables and intended use
Participant	Demographic variables, hernia laterality and participant-level presence of at least one positive hemipelvis.
Hemipelvis	Presence or absence, side, and anatomical type of corona mortis.
Individual vessel	Arterial or venous vessel classification and measured diameter in millimeters.

For analyses involving vessel diameter, each individual vessel is the unit of analysis. Arterial and venous vessels identified in a combined-type hemipelvis are entered and analyzed separately. For analyses described as using the dominant vessel, the dominant vessel is defined as the vessel with the largest measured diameter within the relevant hemipelvis.

6. Analysis Populations

Enrolled population: All participants enrolled in the observational study.

Evaluable hemipelvis population: All surgically examined hemipelves with a recorded presence/absence assessment.

Corona mortis-positive hemipelvis population: All evaluable hemipelves in which at least one arterial and/or venous corona mortis vessel was identified.

Evaluable vessel population: All individual identified vessels with a valid arterial/venous classification and interpretable diameter measurement.

Bilateral paired population: Participants undergoing bilateral repair with evaluable presence/absence data for both right and left hemipelves.

7. General Statistical Principles

- All analyses are descriptive unless an exploratory hypothesis test is explicitly stated.
- All statistical tests are two-sided. A nominal p-value below 0.05 is considered statistically significant for exploratory interpretation.
- Categorical variables are summarized using counts and percentages. Denominators are reported explicitly when they differ from the full analysis population.
- Continuous variables are summarized using mean, standard deviation, median, minimum and maximum when appropriate.
- No missing-value imputation is performed. Analyses use all available evaluable observations for the relevant endpoint.
- No interim analyses, stopping rules or formal confirmatory testing hierarchy are planned.
- No formal adjustment for multiple comparisons is applied. All p-values from subgroup and association analyses are nominal and exploratory.

8. Analysis of Protocol-Defined Outcomes

8.1 Presence of corona mortis

- The primary denominator is the number of evaluable hemipelves.
- Presence and absence are summarized as counts and percentages overall and separately for right and left hemipelves.
- At participant level, the number and percentage of participants with at least one corona mortis-positive hemipelvis are summarized separately for unilateral and bilateral hernia groups.

Exploratory comparisons: Pearson chi-square test is used for categorical comparisons when expected cell counts are adequate. Fisher exact test is used when expected counts are small. Right-left paired presence among participants with bilateral repair is evaluated using the exact McNemar test.

8.2 Anatomical type of corona mortis

- The analysis population consists of corona mortis-positive hemipelves.

- Anatomical type is categorized as venous, arterial, or combined arterial and venous.
- Each category is summarized as a count and percentage of positive hemipelvises.

Exploratory age comparison: Age is compared across absent, venous, arterial and combined categories using the Kruskal-Wallis test. If an overall difference is identified, pairwise post hoc comparisons may be performed and clearly labeled as exploratory.

8.3 Diameter of corona mortis vessels

- The analysis unit is the individual evaluable vessel.
- Vessel diameter is summarized overall and separately for arterial and venous vessels using mean, standard deviation, median and range.
- Diameter is additionally summarized by side of the hemipelvis.
- Vessels are grouped into three clinically descriptive diameter categories: small (≤ 2 mm), medium (>2 to ≤ 5 mm), and large (>5 mm).

Exploratory comparisons: The Mann-Whitney U test is used to compare arterial versus venous diameters and right versus left diameters within each vessel type. Size-category distributions are compared using Pearson chi-square or an exact test when expected counts are insufficient.

9. Exploratory Association Analyses

9.1 Sex and corona mortis presence

Presence/absence by participant sex is summarized at the hemipelvis level using counts and percentages. Pearson chi-square and Fisher exact tests are reported as exploratory analyses. The limited number of female participants is acknowledged when interpreting these comparisons.

9.2 Age and corona mortis presence

Participant age is summarized for corona mortis-positive and corona mortis-negative hemipelvises. The Mann-Whitney U test is the primary exploratory comparison. A Welch two-sample t-test may be reported as a sensitivity analysis because it does not assume equal variances.

9.3 Side and paired bilateral assessment

Right and left hemipelvises are compared descriptively and with an unpaired chi-square test at the hemipelvis level. Because two observations from the same participant are not independent, the exact McNemar test in the bilateral paired population is the preferred within-participant assessment of right-left asymmetry.

9.4 Unilateral versus bilateral hernia

Corona mortis presence is compared between hemipelvises from participants with unilateral and bilateral hernias using a chi-square test. A separate participant-level analysis compares the proportion of participants with at least one positive hemipelvis between unilateral and bilateral groups.

9.5 Age and vessel diameter

The association between participant age and dominant-vessel diameter is assessed using Spearman rank correlation. For descriptive size-category analyses, age is summarized across the small, medium and large diameter groups and compared using the Kruskal-Wallis test.

10. Data Review and Handling Rules

- Categorical entries are standardized before analysis, including side, hernia laterality, vessel type and presence/absence coding.
- Entries indicating more than one vessel in a hemipelvis are separated into individual vessel measurements when the source notation permits unambiguous interpretation.
- Potential spreadsheet auto-formatting errors or ambiguous diameter values are checked against the original operative documentation and intraoperative image when available.
- If an ambiguous diameter cannot be resolved, the vessel is excluded from diameter-based analyses only; valid presence and type information remains eligible for the corresponding analyses.
- Implausible values are queried against source documentation rather than automatically winsorized, truncated or deleted.
- Duplicate records are investigated using the study identifier and source documentation. Confirmed duplicates are removed before analysis.

11. Statistical Tests and Assumption Checks

Method	Use
Pearson chi-square test	Comparison of categorical distributions when expected cell counts are adequate.
Fisher exact test	Two-by-two categorical comparisons with small expected cell counts.
Fisher-Freeman-Halton exact test	May be used for larger contingency tables when chi-square assumptions are not met.
Mann-Whitney U test	Comparison of two independent groups for continuous or ordinal variables without reliance on normality.
Welch t-test	Sensitivity comparison of two means without assuming equal variances.
Kruskal-Wallis test	Comparison of continuous distributions across three or more independent groups.
Exact McNemar test	Paired binary comparison of right and left hemipelvis within participants undergoing bilateral repair.
Spearman rank correlation	Monotonic association between participant age and dominant-vessel diameter.

Distributional shape is reviewed using summary statistics and graphical inspection when available. Exact methods are preferred when asymptotic assumptions are not satisfied. The analysis report will identify the statistical software and version used.

12. Sensitivity and Robustness Considerations

- The participant-level analysis of at least one positive hemipelvis is used to complement hemipelvis-level comparisons and reduce the impact of participants contributing two sides.
- The paired McNemar analysis is used to assess side differences within bilateral participants, complementing the unpaired hemipelvis-level comparison.
- Welch t-test results for age may be presented alongside the Mann-Whitney U test as a sensitivity analysis; the nonparametric result remains the primary exploratory comparison.
- Analyses excluding unresolved or non-interpretable diameter measurements are considered the main vessel-size analyses. The number and reason for excluded measurements are reported.

13. Adverse Events and Mortality

The observational protocol did not define systematic postoperative adverse-event surveillance. For registry reporting, intraoperative all-cause mortality and any adverse events documented during the period from the start to the end of the TEP procedure are summarized using counts of affected participants and participants at risk. No inferential safety analysis is planned.

14. Sample Size

The protocol specified a target enrollment of 300 participants. No formal hypothesis-driven sample-size or statistical-power calculation was documented. The study is therefore interpreted as a descriptive prospective series, and the exploratory p-values do not convert the study into a confirmatory hypothesis-testing design.

15. Reporting Conventions

- Counts are reported as integers and percentages generally to one decimal place.
- Age is generally reported to one decimal place for means and standard deviations.
- Vessel diameter means and standard deviations may be reported to two decimal places; medians and ranges follow the precision of the recorded measurements.
- P-values are generally reported to three decimal places; values below 0.001 are reported as $p < 0.001$ unless a more precise value is scientifically useful.
- Effect estimates and confidence intervals may be added for scientific reporting, but any such additions must be clearly described and must not be presented as prospectively prespecified.

- Interpretation is limited to association and description. Causal language is not used for this observational study.

16. Deviations from This SAP

Any substantive deviation from the methods in this document will be documented in the final analysis report or publication, including the reason for the change and whether the change was made before or after inspection of the relevant results. Because this SAP is post-completion, all analyses remain subject to transparent exploratory interpretation.

17. End of Statistical Analysis Plan

This document contains statistical methods only and does not contain study results, participant-level data, an informed consent form, or a study protocol.