# COMPARISON OF OUTCOMES AND SURGICAL TIME BETWEEN CORTICAL AND MEDULLARY SUTURE VERSUS MEDULLARY-ONLY SUTURE: CORTEX CLINICAL TRIAL

14/09/2025

NCT number: Not available

**Brief Summary**

This randomized, prospective, blinded clinical trial will compare two renorrhaphy techniques in robot-assisted partial nephrectomy: medullary-only suture (single layer) versus cortical and medullary suture (two layers). The study will evaluate estimated blood loss, renal function, warm ischemia time, complication rates, operative efficiency, and hospital length of stay.

**Study Design**

- **Study Type:** Interventional (Clinical Trial)
- **Allocation:** Randomized (1:1)
- **Intervention Model:** Parallel Assignment
- **Masking:** Participant, postoperative care physician, data collectors, and statisticians (surgical team not blinded)
- **Primary Purpose:** Treatment
- **Estimated Enrollment:** 80 participants
- **Study Start Date:** March 2025
- **Estimated Primary Completion Date:** March 2027

**Official Title**

Comparison of Outcomes and Surgical Time Between Cortical and Medullary Suture Versus Medullary-Only Suture: CORTEX Clinical Trial

**Conditions**

Renal Cell Carcinoma; Renal Mass Requiring Partial Nephrectomy

**Interventions**

- **Experimental: Medullary-only suture**
  Robot-assisted partial nephrectomy using single-layer medullary suturing with 3-0 absorbable monofilament poliglecaprone 25 (Caprofyl™), with early unclamping.

- **Active Comparator: Cortical and Medullary suture**
  Robot-assisted partial nephrectomy using two-layer suturing (3-0 Caprofyl™ for medullary layer plus 0 Vicryl™ for cortical layer after early unclamping).

**Primary Outcome Measure**

- **Estimated Blood Loss**
  Volume of blood loss measured intraoperatively.
  **Time Frame:** During surgery (intraoperative period).

**Secondary Outcome Measures**

- **Renal Function (eGFR)**
  Estimated glomerular filtration rate using CKD-EPI at baseline and at postoperative day 1, 2 weeks, 2 months, and 5 months.
  **Time Frame:** Baseline, Day 1, 2 weeks, 2 months, and 5 months postoperatively.
- **Percentage of Renal Volume Loss**
  Difference between preoperative and postoperative renal volume measured on imaging.
  **Time Frame:** 4 months postoperatively.
- **Warm Ischemia Time**
  Duration of renal artery clamping during surgery.
  **Time Frame:** Intraoperative (minutes of arterial clamping).
- **Complications (hematuria, pseudoaneurysm, urinary fistula)**
  Incidence of intra- and postoperative complications.
  **Time Frame:** From surgery through 5 months postoperatively.
- **Console Time**
  Duration from docking to undocking of the robotic system.
  **Time Frame:** Intraoperative.
- **Length of Hospital Stay**
  Number of days from surgery to hospital discharge.
  **Time Frame:** From day of surgery until hospital discharge.
- **Conversion to Open Surgery**
  Number of cases converted to open surgery.
  **Time Frame:** Intraoperative.
- **Postoperative Quality of Life (WHOQOL-BREF)**
  Score on WHOQOL-BREF questionnaire.
  **Time Frame:** 2 months and 5 months postoperatively.

**Eligibility Criteria**

**Inclusion Criteria:**

- Age ≥18 years
- Indication for robot-assisted partial nephrectomy due to renal mass diagnosed on CT
- ECOG performance status ≤1
- Negative pregnancy test within 24 h preoperatively for women of childbearing potential
- Written informed consent

**Exclusion Criteria:**

- Solitary kidney
- Multiple or bilateral renal masses (if operated simultaneously or within <4 months)
- GFR <30 mL/min/1.73m² or grade ≥2 hepatic/renal toxicity
- Bleeding diathesis or inability to maintain anticoagulation
- Participation in another experimental trial within 30 days
- Significant acute or chronic conditions compromising safety or study compliance

**Study Locations**

Mater Dei Hospital, Salvador, Bahia, Brazil
Santa Izabel Hospital – Santa Casa, Salvador, Bahia, Brazil

**Statistical Analysis**

Descriptive statistics for all variables. Student's t-test or Wilcoxon for continuous variables; chi-square or Fisher's exact test for categorical variables. Multiple logistic and linear regression analyses for adjusted associations. $p<0.05$ considered significant. Statistical software: R version 4.4.2.

**Arms and Interventions**

| Arm/Group | Intervention Name | Intervention Description |
|---|---|---|
| Experimental: Medullary-only Suture | Medullary-only suture (Caprofyl™ 3-0) | Robot-assisted partial nephrectomy using single-layer medullary suturing with 3-0 absorbable monofilament poliglecaprone 25 (Caprofyl™) and early unclamping. |

| Arm/Group | Intervention Name | Intervention Description |
|---|---|---|
| Active Comparator: Cortical and Medullary Suture | Cortical + Medullary suture (Caprofyl™ + Vicryl™) | Robot-assisted partial nephrectomy using two-layer suturing (3-0 Caprofyl™ for medullary layer plus 0 Vicryl™ for cortical layer after early unclamping). |

**Outcome Measures Table (PRS-ready)**

| Title | Description | Time Frame | Safety Issue? |
|---|---|---|---|
| Estimated Blood Loss (Primary Outcome) | Volume of blood lost during surgery, measured intraoperatively using suction canisters and swab weight. | During surgery (intraoperative period) | No |
| Renal Function (eGFR) | Estimated glomerular filtration rate (CKD-EPI) at baseline and at postoperative time points. | Baseline, Day 1, 2 weeks, 2 months, and 5 months postoperatively | No |
| Percentage of Renal Volume Loss | Difference between preoperative and postoperative renal volume measured by imaging. | 4 months postoperatively | No |
| Warm Ischemia Time | Duration of renal artery clamping during surgery in minutes. | Intraoperative | No |
| Complications (hematuria, pseudoaneurysm, urinary fistula) | Incidence of intra- and postoperative complications recorded from medical records. | From surgery through 5 months postoperatively | Yes |
| Console Time | Duration from robotic docking to undocking. | Intraoperative | No |

| Title | Description | Time Frame | Safety Issue? |
|---|---|---|---|
| Length of Hospital Stay | Number of days from surgery to hospital discharge. | From day of surgery until hospital discharge | No |
| Conversion to Open Surgery | Number of cases converted from robotic to open surgery. | Intraoperative | No |
| Postoperative Quality of Life (WHOQOL-BREF) | Score on WHOQOL-BREF questionnaire assessing quality of life. | 2 months and 5 months postoperatively | No |