Official Title of the study

Negative prEssure Wound thErapy in Renal transplant - NEWER trial

NCT number - not yet assigned

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Study Protocol: Negative prEssure Wound thErapy in Renal transplant - NEWER trial

Brief Summary

Renal transplant recipients are at increased risk for postoperative wound complications such as dehiscence, infection, and delayed healing, which may lead to graft failure, prolonged hospitalization, and increased healthcare costs. The NEWER study is a randomized, open-label, controlled trial evaluating the effectiveness of prophylactic negative pressure wound therapy (NPWT) compared to standard dressings in reducing wound complications after renal transplantation.

Study Details

Study Type: Interventional (Clinical Trial)
Estimated Enrollment: 150 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label) Primary
Purpose: Prevention
Study Start Date: January 2023
Estimated Primary Completion Date: August 2024
Estimated Study Completion Date: November 2024
Study Phase: Phase II-equivalent (non-drug intervention)

Conditions Studied

- Postoperative wound dehiscence
- Wound infection
- Renal transplantation

Interventions

Arm 1: NPWT Group
Intervention: Application of Negative Pressure Wound Therapy
Device: PICO™ System (Smith & Nephew)
Procedure: Applied intraoperatively at −80 mmHg and maintained continuously for 7 days over the closed surgical incision.

Arm 2: Standard Dressing Group
Intervention: Conventional postoperative wound care with gauze-based dressing per institutional protocol.

Outcome Measures

Primary Outcome:
1. Incidence of Wound Dehiscence (Day 0 to Day 90)
   - Superficial or deep dehiscence classification

Secondary Outcomes:
1. Wound Infection (ASEPSIS score) at Days 7, 14, 30, and 90
2. Pain (Visual Analogue Scale, 0–10) at Days 7, 14, 30, and 90
3. Scar Healing (POSAS Score) at Days 7, 14, 30, and 90
4. Quality of Life (EQ-5D) at Pre-op Days 7, 14, 30, and 90
5. Hospital Stay Duration
6. Graft Function (serum creatinine, eGFR at Day 90)

Eligibility Criteria

Inclusion:
- Adults (≥18 years) undergoing elective open renal transplant
- Informed consent provided

Exclusion:
- Age <18 years
- Allergies to NPWT components
- Surgical reintervention within first 3 postoperative months
- Pregnant or breastfeeding women
- Active skin infection or dermatologic condition at surgical site

Study Locations

- São João University Hospital, Porto, Portugal

Contacts

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Ethical Considerations

The study has been approved by the Institutional Review Board (IRB) of São João University Hospital.

Registration Statement

This study will be registered on ClinicalTrials.gov in accordance with ICMJE and WHO trial registration policies.

Statistical Analysis Plan

All statistical analyses will be performed using SPSS. A two-sided p-value < 0.05 will be considered statistically significant.

Descriptive statistics will be used to summarize baseline characteristics. Continuous variables will be presented as mean ± standard deviation or median with interquartile range, depending on the data distribution. Categorical variables will be expressed as frequencies and percentages.

Primary Outcome:

- Incidence of wound dehiscence will be compared between NPWT and Standard groups using the chi-square test or Fisher's exact test.

Secondary Outcomes:
- ASEPSIS scores and pain scores (VAS) will be compared using t-tests or Mann–Whitney U tests, depending on normality.
- POSAS scores and EQ-5D index values will be analyzed similarly.
- Length of hospital stay and graft function will be analyzed using t-tests or nonparametric equivalents.

Multivariable logistic regression may be used to adjust for potential confounding variables influencing wound outcomes.

Missing Data:
- Multiple imputation will be considered if missing data exceeds 5% for primary outcomes. Sensitivity analyses will be conducted to test robustness of findings.