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TRANSPLANT-NEPHROLOGY DEPARTMENT

STUDY TITLE

Physical Performance Assessment in Kidney Transplant Evaluation Using the Short Physical Performance Battery (SPPB)

(FRAIL-KTx)

NCT number:

In Martin, Slovakia 9th JULY 2025

Transplantačno – Nefrologické oddelenie Univerzitná nemocnica Martin

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Brief Description

This prospective cohort study investigates physical frailty, assessed by the Short Physical Performance Battery (SPPB), in patients evaluated for kidney transplantation. The study aims to compare SPPB scores before listing, annually during the waiting period, and after transplantation at 6 and 12 months. It also includes a control group of dialysis patients not eligible for transplantation to evaluate differences in physical performance. The goal is to understand how frailty impacts transplant outcomes and patient recovery.

Detailed Description

This longitudinal, prospective study focuses on assessing the role of physical frailty in patients undergoing evaluation for kidney transplantation using the Short Physical Performance Battery (SPPB). The study will enroll adult patients who are being assessed for kidney transplantation, including those who are deemed suitable and placed on the waiting list (Arm A) and those on dialysis who are considered unsuitable for transplant listing (Arm B).

Participants will undergo comprehensive SPPB assessments at baseline, during their evaluation process, and subsequently at annual follow-up intervals. For listed patients, the assessments will be performed upon initial evaluation, then annually while on the waiting list, and at 6 and 12 months following transplantation. For patients ineligible for the transplant list and on dialysis, the SPPB will be recorded at baseline and then annually, allowing cross-sectional comparison and understanding of their physical performance trajectory.

The primary objective is to evaluate changes in physical performance over time with the SPPB score, which ranges from 0 to 12. The scores will be used to categorize participants into frail, pre-frail, or non-frail groups, providing insights into the prevalence and evolution of frailty in this population.

Secondary objectives include comparing the baseline and follow-up SPPB scores between the two arms, correlating physical performance with post-transplant outcomes such as graft function and survival, and identifying potential predictors of frailty that could inform prehabilitation interventions.

This study may inform future strategies to optimize physical function in kidney transplant candidates and improve clinical outcomes through targeted interventions addressing physical frailty.

Study Design:

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1. Study Overview

This prospective cohort study aims to assess physical frailty using the Short Physical Performance Battery (SPPB) among patients undergoing kidney transplant evaluation. The study will track physical performance changes before listing, annually for those listed, and at 6 and 12 months post-transplant. A comparison will be made between patients on the transplant waiting list and those on dialysis who are not eligible for listing.

2. Study Design

- **Type:** Longitudinal, prospective cohort study.
- **Duration:** 3-5 years.
- **Participants:** Adult patients undergoing kidney transplant evaluation.

3. Objective

- **Primary Objective:** To assess changes in physical performance using SPPB scores before and after kidney transplantation.
- **Secondary Objective:** To compare SPPB scores between patients on the waiting list and those on dialysis not eligible for the list.

4. Methodology

Inclusion Criteria:

1. Adult patients (≥18 years) undergoing evaluation for kidney transplantation.
2. Patients on dialysis.
3. Ability and consent to participate.

Exclusion Criteria:

1. Non-adult patients.
2. Patients unable to provide informed consent.
3. Acute medical conditions prohibiting SPPB assessment.

Study Arms:

- **Arm A:** Patients eligible and listed for kidney transplantation.
- **Arm B:** Dialysis patients not suitable for the waiting list.

SPPB Assessment:

- Measurement of physical performance including:
  - Balance tests (side-by-side, semi-tandem, tandem stands)
  - Gait speed (over a short distance)
  - Repeated chair stands

Data Collection:

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- **Baseline:** During initial evaluation for kidney transplantation.
- **Follow-up:** Annually for listed patients; at 6 and 12 months post-transplantation.

5. Statistical Analysis

- **Sample Size:** Estimated 200 patients (100 per arm) to ensure sufficient statistical power.
- **Statistical Tests:**
  - Descriptive statistics for baseline characteristics.
  - Paired t-tests or Wilcoxon signed-rank tests for changes in SPPB scores.
  - Chi-square tests for categorical outcomes.
  - Mixed-effects models to analyze longitudinal SPPB score changes.
  - Kaplan-Meier analysis for survival outcomes related to frailty status.

6. Expected Outcomes

- Characterization of physical performance levels in patients considered for kidney transplantation.
- Identification of changes in physical performance post-transplant.
- Comparison of frailty progression in patients eligible vs. ineligible for the transplant list.

7. Ethical Considerations

- Informed consent will be obtained from all participants.
- Approval from the institutional review board will be secured.

8. Conclusion

This study will provide crucial insights into the implications of physical frailty, as assessed by SPPB, in the context of kidney transplantation. The findings will help in formulating intervention strategies to improve patient outcomes.

Methodology (Detailed)

SPPB Assessment Procedure:

The **Short Physical Performance Battery (SPPB)** evaluates lower extremity function through three components, each scored on a standardized scale. The total SPPB score ranges from **0 to 12**, with higher scores indicating better physical performance and lower frailty levels.

Components and Scoring:

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1. Balance Tests (Maximum score: 4 points)

- **Side-by-side Stand:**
  - Held for 10 seconds → 1 point
  - Unable to hold for 10 seconds → 0 points
- **Semi-tandem Stand:**
  - Held for 10 seconds → 1 point
  - Unable to hold for 10 seconds → 0 points
- **Tandem Stand:**
  - Held for 10 seconds → 2 points
  - Unable to hold for 10 seconds → 0 points

  Overall balance score: Sum of these tests, capped at 4 points.

2. Gait Speed (Maximum score: 4 points)

- Time to walk 4 meters (standardized corridor):
  - **> 4.82 seconds:** 0 points
  - **3.00 – 4.82 seconds:** 1 point
  - **< 3.00 seconds:** 2 points

3. Repeated Chair Stands (Maximum score: 4 points)

- Time to rise from a chair 5 times:
  - **> 16.7 seconds:** 0 points
  - **11.2 – 16.7 seconds:** 1 point
  - **< 11.2 seconds:** 2 points

Note: For all components, the best possible score per sub-test is reached if the participant can perform the task within the ideal time or balance parameters.

Scoring Interpretation:

Total Score	Frailty Status
0–6	Frail
7–9	Pre-frail
10–12	Robust/Non-frail (Normal physical performance)

Assessment Protocol:

- **Baseline:** During initial transplant evaluation, clinicians will perform the SPPB following standardized procedures.
- **Follow-up:** The same assessments will be repeated at annual intervals for listed patients and at 6 and 12 months post-transplant.

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- **Data Recording:** All scores will be documented in the study database, ensuring consistency and reliability.

Additional Notes:

- Assessments should be performed by trained personnel to ensure consistency.
- Patients will be allowed rest between components to prevent fatigue.
- Adaptations will be made for patients with mobility aids, if necessary, but these will be noted.

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