Study Protocol with Informed Consent Form

Title: A Single-Center, Prospective, Open-Label, Self-Controlled Clinical Study on the Efficacy and Safety of Amino Acid (15) Peritoneal Dialysis Solution in Improving Nutritional Status of Peritoneal Dialysis Patients

Version No.: 1.0

Version Date: December 10, 2025

IRB Approval No.: SHSY-IEC-6.0/26K8/P01

IRB Approval Date: January 9, 2026

Sponsor: Shanghai Tenth People's Hospital

Principal Investigators: Xue Wen

Department: Department of Nephrology

1. Study Objectives

1.1 Primary Objective

To evaluate the efficacy of Amino Acid (15) Peritoneal Dialysis Solution in improving the nutritional status of patients receiving peritoneal dialysis.

1.2 Secondary Objectives

- Observe the effects of the solution on dialysis adequacy and peritoneal transport function.
- Monitor adverse events and complications to assess the short-term safety of the solution.

1.3 Exploratory Objective

To explore the mechanism by which Amino Acid (15) Peritoneal Dialysis Solution improves nutritional status in peritoneal dialysis patients through intra-abdominal amino acid supplementation.

2. Study Design

- **Study Type**: Interventional clinical study
- **Design**: Single-center, prospective, open-label, self-controlled (before-and-after comparison)

- **Total Study Duration**: 24 months (from study initiation to final report completion)
- **Intervention Period per Participant**: 6 months (starting on the enrollment day)
- **Sample Size**: 50 participants

3. Study Population

3.1 Inclusion Criteria

- Aged ≥ 18 years.
- Receiving peritoneal dialysis for ≥ 6 months.
- Serum albumin level < 38 g/L.
- No history of peritonitis in the past 3 months and no hospitalization in the past 1 month.
- No severe heart, liver, or other organ dysfunction, or malignant tumors.
- Expected survival time > 1 year.
- Good compliance and willingness to sign the informed consent form.
- Diagnosed with end-stage renal disease (ESRD) with estimated glomerular filtration rate (eGFR) < 15 mL/ (min·1.73 m^2).

3.2 Exclusion Criteria

- Hypersensitivity or allergy to Amino Acid (15) Peritoneal Dialysis Solution or any of its components.
- Hepatic dysfunction (ALT/AST ≥ 2 times the upper limit of normal).
- Taking medications that affect protein metabolism and unable to maintain a stable dose during the study.
- Need for adjustment of nutritional supplement doses during the study.
- Uncorrectable severe gastrointestinal reactions.
- Pregnant, lactating, or planning to undergo kidney transplantation.

3.3 Withdrawal/Termination Criteria

3.3.1 Participant Withdrawal

- Failure to undergo dialysis as per protocol for 3 consecutive days.
- Two consecutive missed follow-up visits.

- Voluntary withdrawal by the participant.
- Intervention duration < 3 months.

3.3.2 Participant Exclusion

- Missing data > 10% of required outcome measures.
- Severe violation of the study protocol.

3.3.3 Early Study Termination

- Incidence of serious adverse events (SAEs) > 10%.
- No clinically meaningful differences in the primary outcome measure identified by the Data Monitoring Committee.
- Uncontrollable study bias or operational difficulties.

4. Intervention Measures

4.1 Intervention Product

Amino Acid (15) Peritoneal Dialysis Solution (2 L/bag, manufactured by Shandong Weigao Group).

4.2 Administration Protocol

- Participants maintain their original peritoneal dialysis regimen throughout the study.
- Replace one bag of conventional glucose-based dialysis solution with Amino Acid (15) Peritoneal Dialysis Solution after lunch, once daily.
- Continuous intervention for 6 months per participant.
- Dose adjustment: The 2 L/dose is maintained unless safety issues arise (e.g., severe metabolic acidosis), which will be managed with oral sodium bicarbonate as clinically indicated.

4.3 Concomitant Medications

- Participants must maintain stable doses of medications affecting protein metabolism and nutritional supplements throughout the study period.
- Any necessary dose adjustments due to severe clinical complications (e.g., severe infection) will result in participant withdrawal, with follow-up until symptoms stabilize.

5. Outcome Measures

5.1 Primary Outcome Measure

Serum albumin (Alb) level: Measured at baseline (enrollment day), 3 months, and 6 months post-intervention.

5.2 Secondary Outcome Measures

Category	Indicators	Assessment Time Points
Nutritional Status	Prealbumin (PA), Subjective Global Assessment (SGA) score, Transferrin (TF), Lean Body Mass (LBM), Grip strength, Mid-Arm Muscle Circumference (MAMC), Blood amino acid profile	Baseline, 6 months post-intervention
Dialysis Adequacy	Total Kt/Vurea, Peritoneal Creatinine Clearance (Ccr)	Baseline, 6 months post-intervention
Peritoneal Transport Function	Creatinine Mass Transfer Area Coefficient (MTACcr), Dialysate Urea-Creatinine Ratio (R-Ccr)	Baseline, 6 months post-intervention
Dialysis-Related	Ultrafiltration Volume (UF)	Every 2 weeks during intervention

5.3 Safety Outcome Measures

- Adverse events (AEs): Including peritonitis, gastrointestinal reactions (e.g., abdominal distension, diarrhea), metabolic acidosis, etc.; recorded throughout the study period.
- Serious adverse events (SAEs): Including death, life-threatening events, prolonged hospitalization, permanent disability, etc.; reported to the Ethics Committee and sponsor within 24 hours of identification.

6. Study Procedures

6.1 Timeline

Phase	Duration	Key Activities
Preparation & Rolling Recruitment	January 2026 – June 2027 (18 months)	Screen participants, verify eligibility, obtain informed consent, complete baseline assessments (recruitment continues until 6 months before study end to ensure all participants finish 6-month follow-up)
Intervention & Follow-up (Per Participant)	6 Months Post-Enrollment	Implement intervention, conduct biweekly follow-up (record UF and AEs), perform 3-month serum albumin testing
Final Post-Intervention & Study Closure	July 2027 – December 31, 2027 (6 months)	Complete 6-month outcome assessments for the last enrolled participants; finalize data verification, statistical analysis, and study report writing

6.2 Specific Procedures

1. **Baseline Assessment (Enrollment Day)**: Collect demographic data, perform physical examination, conduct laboratory tests (blood, urine, dialysate samples), evaluate peritoneal function, complete SGA scoring, and measure muscle mass.
2. **Intervention Period**: Conduct biweekly follow-up to record UF volume, AEs and assess medication compliance. Perform serum Alb testing and AE review at the 3-month follow-up.
3. **6-Month Post-Intervention**: Repeat all baseline assessments to measure outcome indicators.
4. **Withdrawal Visit**: Complete safety assessments and data supplementation for participants who withdraw from the study.

7. Statistical Analysis Plan

7.1 Statistical Software

SPSS 26.0

7.2 Data Analysis Principles

- **Intention-to-Treat (ITT) Analysis**: All enrolled participants will be included in the ITT set, regardless of protocol adherence.
- **Per-Protocol (PP) Analysis**: Participants who complete the full intervention and have no major protocol violations will be included in the PP set for sensitivity analysis.

7.3 Descriptive Statistics

- Continuous data: Presented as mean ± standard deviation (SD) if normally distributed, or median (interquartile range [IQR]) if non-normally distributed.
- Categorical data: Presented as counts (percentages).

7.4 Inferential Statistics

- **Primary Outcome**: Compare serum Alb levels before and after intervention using paired t-tests (if normally distributed) or Wilcoxon signed-rank tests (if non-normally distributed).
- **Secondary Outcomes**: Use the same statistical methods as the primary outcome for continuous indicators; use Chi-square tests or Fisher's exact tests for categorical safety indicators.
- **Correlation Analysis**: Use Pearson or Spearman correlation tests to explore associations between nutritional indicators and other outcomes.
- **Significance Level**: Two-tailed $\alpha = 0.05$.

7.5 Sample Size Justification

Based on a pre-study pilot (n=20), the standard deviation (σd) of serum Alb changes is 4 g/L, and the clinically meaningful difference (δ) is 3 g/L. With a two-tailed α=0.05 and power=80%, the minimum sample size is 14. Accounting for a 15% withdrawal rate, 50 participants are enrolled to ensure result robustness.

7.6 Missing Data Handling

Missing data will be addressed using multiple imputation methods to minimize bias in the analysis results.

8. Data Management & Quality Control

- **Data Collection**: Use Electronic Case Report Forms (eCRFs) combined with paper records; anonymize data using unique study IDs to protect participant privacy.
- **Data Verification**: Implement double data entry, with all modifications tracked and documented in the audit trail.
- **Equipment Calibration**: Calibrate testing instruments every 3 months to ensure measurement accuracy.
- **Personnel Training**: Provide uniform training on study protocols and Standard Operating Procedures (SOPs) to all study personnel before study initiation.
- **Metadata Removal**: Redact and remove metadata from all electronic documents before submission to ensure compliance with data privacy regulations.

9. Ethics & Compliance

- The study complies with the 2024 Declaration of Helsinki, Good Clinical Practice (GCP), and relevant national regulations.
- Approved by the Ethics Committee of Shanghai Tenth People's Hospital (Approval No.: SHSY-IEC-6.0/26K8/P01; Approval Date: January 9, 2026).
- Informed consent will be obtained from all participants (or legal representatives) before enrollment.
- All personally identifiable information (PII) and confidential commercial information will be redacted before any public disclosure.

Informed Consent Form

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Introduction

You are invited to participate in a single-center clinical study conducted by the Department of Nephrology, Shanghai Tenth People's Hospital. This study has been approved by the hospital's Ethics Committee. It is important that you understand the study's purpose, procedures, benefits, and risks before deciding to participate. Please read this form carefully, and feel free to discuss it with your family or ask the researchers any questions you may have.

1. Study Purpose

This study aims to evaluate whether Amino Acid (15) Peritoneal Dialysis Solution can improve the nutritional status of patients receiving peritoneal dialysis. It will also observe the solution's effects on dialysis adequacy and peritoneal transport function, and monitor its short-term safety. Additionally, blood, urine, and dialysate samples will be collected for related research purposes.

2. Study Procedures

If you meet the eligibility criteria and agree to participate:

1. **Baseline Assessment**: On the enrollment day, you will undergo physical examinations, laboratory tests, and nutritional status evaluations.
2. **Intervention**: You will continue your regular peritoneal dialysis regimen, replacing one bag of dialysis solutions with Amino Acid (15) Peritoneal Dialysis Solution (2 L/bag) after lunch, once daily, for 6 months.
3. **Follow-up**: You will need to attend follow-up visits at the hospital on the enrollment day (baseline), 3 months, and 6 months post-intervention. Biweekly check-ins will also be conducted to record your dialysis data and any discomfort you may experience.
4. **Compliance Requirements**: Please report any changes in your health or medication use to the researchers promptly. Do not adjust medication doses without medical advice.

3. Risks

- **Routine Medical Risks**: Blood tests may cause mild pain or bruising. Peritoneal dialysis-related procedures carry a risk of infection (e.g., peritonitis), similar to your regular dialysis.
- **Solution-Related Reactions**: Mild gastrointestinal symptoms (e.g., abdominal distension, diarrhea) may occur rarely, which usually improve with dose adjustment.
- **Metabolic Risks**: Transient metabolic acidosis (low blood bicarbonate) may occur. Doctors will provide oral sodium bicarbonate to correct it if needed.

4. Benefits

- You may experience improved nutritional status and stable dialysis adequacy.
- You will receive dedicated follow-up care from Dr. Xue Wen and the study's interdisciplinary treatment team, with free professional consultations.
- More frequent and comprehensive medical monitoring will help detect and address dialysis-related issues early.

Note: Due to individual differences, we cannot guarantee that all participants will achieve the expected benefits.

5. Rights

- Participation is voluntary. You may withdraw from the study at any time without affecting your regular medical care or legal rights.
- If you withdraw, you will no longer receive study-specific benefits (e.g., dedicated follow-up), but your routine dialysis treatment will continue as usual.
- All your personal and medical information will be kept confidential. Electronic records will be anonymized with study IDs, and paper records will be stored securely. No identifying information will be included in study publications.

6. Contact Information

For questions about the study, please contact:

Dr. Xue Wen

Phone: 19946074784

Consent Statement

I voluntarily agree to participate in this study.

I have been informed of the study's purpose, procedures, risks, and benefits. I have read this consent form (provided in a language I understand), had the opportunity to ask questions, and all my questions have been answered to my satisfaction.

I agree to the collection and use of my health information for research purposes.

I understand I may withdraw from the study at any time without penalty.

I acknowledge that signing this form does not waive any of my legal rights.

I will receive a copy of this signed consent form, and the original will be retained by the study center.

Signature	Date
Participant's Signature	
Legal Representative's Signature (if applicable)	
Witness's Signature (if participant cannot read)	
Investigator's Signature	