ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 9, 2025

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	Alaa-02012024
Brief Title:	Effect of Intradialytic Blood Flow Restriction Training on Functional Capacity, Estimated Glomerular Filtration Rate and Health Related Quality of Life in Patients on Hemodialysis
Official Title:	Effect of Intradialytic Blood Flow Restriction Training on Functional Capacity, Estimated Glomerular Filtration Rate and Health Related Quality of Life in Patients on Hemodialysis
Secondary IDs:	

Study Status

Record Verification:	May 2025
Overall Status:	Completed
Study Start:	August 1, 2024 [Actual]
Primary Completion:	November 15, 2024 [Actual]
Study Completion:	December 15, 2024 [Actual]

Sponsor/Collaborators

Sponsor:	Beni-Suef University
Responsible Party:	Principal Investigator Investigator: Alaa Sayed Abd El Aziz [asaeaziz] Official Title: principal investigator Affiliation: Beni-Suef University
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: FMBSUREC/02012024 Board Name: Research Ethical committee Board Affiliation: Ethical committee for human research at faculty of medicine beni-suef university Phone:

Email: Rec.fm@med.bsu.edu.eg
Address:

Beni-suef University

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: this study was done to investigate the effect of intradialytic blood flow restriction training on functional capacity, estimated glomerular filtration rate and health related Quality of life in patients on Hemodialysis

Detailed Description: Chronic kidney disease affects 10% to 15% of the population and is characterized by a progressive decline in glomerular filtration rate. The disease can lead to frailty, muscle mass wasting, and sarcopenia, affecting functional mobility and quality-of-life measures. The increased protein catabolism in Chronic kidney disease is partly due to inflammatory status, nutrient loss during dialysis, and musculoskeletal system changes. Assessment of muscle functionality can provide additional diagnostic and prognostic information for clinical outcomes, quality of life, and mortality rates. Exercise training with blood flow restriction is a potential method for clinical musculoskeletal rehabilitation, potentially improving strength, physical function, blood pressure control, glucose homeostasis, autonomic function, renal deterioration, dialysis adequacy, and antioxidant defenses.

Conditions

Conditions: Blood Flow Restriction Training
Glomerular Filtration Rate
Quality of Life
Hemodialysis

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 30 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: blood flow restriction Included 15 chronic kidney disease patients on hemodialysis received conventional exercise program	conventional exercise Program Exercises include shoulder flexion, shoulder abduction, leg extension, and hand grip. Start with

Arms	Assigned Interventions
included isometric, aerobic, and resisted exercise individualized for every patient with blood flow restriction by 50% of limb occlusion Pressure. training was conducted for 2 time/weak for 2 consecutive month	1-3 sets of 12 reps at 30% of 1-repetition maximum, increasing by 10% according to patient endurance. Cycling is a 30-minute chair or bedside cycle ergometer exercise 2 time/weak for 2 consecutive months blood flow restriction training Patients received the same conventional exercise program, which included isometric, aerobic, and resisted exercise individualized for every patient with blood flow restriction by 50% of limb occlusion pressure. Training will be conducted for 2 time/weak for 2 consecutive month
Active Comparator: conventional exercise Program Included 15 chronic kidney disease patients on hemodialysis received conventional exercise program only included isometric, aerobic, and resisted exercise individualized for every patient. training was conducted for 2 time/weak for 2 consecutive month	conventional exercise Program Exercises include shoulder flexion, shoulder abduction, leg extension, and hand grip. Start with 1-3 sets of 12 reps at 30% of 1-repetition maximum, increasing by 10% according to patient endurance. Cycling is a 30-minute chair or bedside cycle ergometer exercise 2 time/weak for 2 consecutive months

Outcome Measures

Primary Outcome Measure:

1. assessment of change of estimated glomerular filtration rate
   Estimated glomerular filtration rate (eGFR) was calculated using the Chronic Kidney Disease Epidemiology Collaboration Creatinine Equation (2021) as recommended by the National Kidney Foundation to assess renal function and detect deterioration.

   [Time Frame: at baseline and after 8 weeks]

Secondary Outcome Measure:

2. assessment of change of Limb Occlusion Pressure
   Limb occlusion pressure was measured using a vascular Doppler ultrasound in combination with a blood flow restriction device to determine individualized occlusion thresholds.

   [Time Frame: at baseline and after 8 weeks]
3. assessment of change of Glucose Homeostasis
   Glucose regulation was assessed through glycated hemoglobin (HbA1c) levels, reflecting average blood glucose over the previous 2–3 months

   [Time Frame: at baseline and after 8 weeks]
4. assessment of change of upper limb Muscle Strength
   Upper limb strength was measured using a handgrip dynamometer.

   [Time Frame: at baseline and after 8 weeks]
5. assessment of change of lower limb Muscle Strength
   lower limb strength was assessed using the One-Repetition Maximum (1RM) test to determine maximum voluntary strength

   [Time Frame: at baseline and after 8 weeks]

Eligibility

Minimum Age: 40 Years

Maximum Age: 60 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

All patients were

1. Both sex aged from forty to sixty years
2. Stable chronic hemodialysis patient (< 3 months)
3. Participants will be deemed medically eligible by their treating physician before participation in the present study
4. Free from any other disease could interfere with exercise

Exclusion Criteria:

1. Hemodynamic instability during hemodialysis over the last month
2. Neurodegenerative diseases
3. Autoimmune diseases (i.e., lupus erythematosus)
4. Surgery within the past 3 months
5. Severe arrhythmia, angina or cerebrovascular disease
6. Unstable on dialysis
7. Any musculoskeletal problem interfere with exercise

Contacts/Locations

Central Contact Person: Alaa Sayed Abd el-Aziz, physical therapist
Telephone: 01222870292
Email: alaazezo53@gmail.com

Central Contact Backup:

Study Officials:

Locations: **Egypt**
out-patient clinic, faculty of physical therapy, beni-suef University
Banī Suwayf, Egypt
Contact: Alaa Sayed Abd-Elaziz, physical therapist 01222870292
alaazezo53@gmail.com

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information: