ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 29, 2020

ClinicalTrials.gov ID: NCT04608422

Study Identification

Unique Protocol ID:	CKF_BES
Brief Title:	Bioeletric Stimulation in Patients With Chronic Kidney Failure
Official Title:	Bioelectric Stimulation to Improve Kidney Function and Sarcopenia in Patients on Hemodialysis: Randomized Controlled Trial
Secondary IDs:	

Study Status

Record Verification:	October 2020
Overall Status:	Not yet recruiting
Study Start:	November 1, 2020 [Anticipated]
Primary Completion:	February 28, 2021 [Anticipated]
Study Completion:	April 30, 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	Federal University of Health Science of Porto Alegre
Responsible Party:	Principal Investigator Investigator: Rodrigo Della Méa Plentz [rplentz] Official Title: Principal Investigator Affiliation: Federal University of Health Science of Porto Alegre
Collaborators:	Irmandade Santa Casa de Misericórdia de Porto Alegre Leonhardt Ventures LLC

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 4.225.654 Board Name: Human Research Ethics Committee of Santa Casa de Misericórdia de Porto Alegre Board Affiliation: Irmandade Santa Casa de Misericórdia de Porto Alegre Phone: +55(51)3214-8571 Email: cep@santacasa.tche.br

Address:	
Data Monitoring:	Yes
FDA Regulated Intervention:	No

Study Description

Brief Summary: This study aims to evaluate the effects of electrical stimulation on renal function and physical capacity in patients with chronic kidney disease (CKD). This is a randomized controlled trial with patients from the HD outpatient of Santa Clara hospital at Irmandade Santa Casa de Misericórdia de Porto Alegre (ISCMPA), who will be allocated to a control group (it will be evaluated and reassessed) or intervention group (it will receive electrical stimulation). Interventions will occur during the HD session, twice a week, for eight weeks, totaling 16 sessions. The groups will be evaluated prior to physiotherapy intervention and at the end. The following outcomes will be measured: renal function, functional capacity, muscle strength of lower limbs and quality of life.

Detailed Description: Chronic kidney disease consists of kidney damage, with consequent progressive and irreversible loss of kidney function. Lower circulating levels of α-klotho protein are related to worsening kidney function and as it is affected, systemic changes occur and lead to the involvement of other organs. Supplementation of soluble α-Klotho protein carried out in experimental studies has been shown to be effective in protecting renal function, in addition to slowing the progression of CKD. Endogenously, physical exercise seems to be a way to increase circulating levels of α klotho. In addition, it is suggested that the contractile activity of the skeletal muscle modulates the expression of circulating Klotho. The practice of physical exercise is considered fundamental in the treatment of patients with CKD, since they present loss of muscle mass and decline in muscle function, and consequently low rates of physical activity and physical inactivity, which is strongly associated with mortality in this population.

As an alternative to mitigate the deleterious effects of sarcopenia in this population, studies have shown beneficial effects of electrical stimulation, such as increased muscle strength, functional capacity and protection against muscle atrophy of the lower limbs. In addition to the clinical and functional effects, electrostimulation reduces DNA damage in patients on hemodialysis (HD), suggesting that electrical stimulation has a systemic effect. In this context, the aim of this study is to evaluate the effects of electrical stimulation on renal function and physical capacity in patients with CKD on HD.

The sample will consist of 20 patients of both sexes, with CKD in stage V of the DRC recruited from the HD outpatient of Santa Clara hospital at ISCMPA. Patients will be randomized into an control or electrical stimulation group. The control group will be evaluated and reassessed. Evaluations will be carried out before and after follow-up: analysis of the plasma content of soluble α-Klotho and creatinine to assess renal function, six-minute walk test (6MWT) to assess functional capacity, sit-and-stand test (STS) with 10 repetitions and dynamometry per load cell to assess muscle strength of lower limbs and application of the EuroQoL-5D questionnaire for quality of life.

Electrical stimulation will be performed during HD, twice a week, for eight weeks, totaling 16 sessions. In the same session, a protocol of neuromuscular electrical stimulation will be applied to quadriceps muscle for 20 min. After, a protocol of sensory electrical stimulation will be applied on kidney anatomical region for 45 min.

At the end of the study, is expected from patients who received electrical stimulation an increase in kidney function and improvement on physical capacity, muscle strength and quality of life.

Conditions

Conditions: Chronic Kidney Disease Stage 5
Electric Stimulation

Keywords:

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: N/A
Interventional Study Model: Parallel Assignment
Number of Arms: 2
Masking: Single (Outcomes Assessor)
Allocation: Randomized
Enrollment: 20 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Electrical stimulation The patients will receive neuromuscular electrical stimulation on quadriceps muscle and sensory stimulation in the anatomical region of the kidneys.	Electrical stimulation A protocol of neuromuscular electrical stimulation will be applied on the quadriceps muscle (symmetric biphasic pulsed current, 80 Hz, 400 µs, 10 s contraction time, 50s/30s/20s rest time, the reciprocal mode, 20 min. After, a protocol of sensory stimulation will be applied on the anatomical region of the kidneys (First: 50 pps, 300 µs, continuous mode for 5 min; Second: 30 pps, 100 µs, continuous mode for 10 min; Third: 20 pps, 1000 µs for 30 min).
No Intervention: Control The patients only will be evaluated and reassessed.	

Outcome Measures

Primary Outcome Measure:

1. Change in soluble α-Klotho protein expression.
   It will be assessed by the analysis of the plasma content by immunoassay assay (ELISA).

   [Time Frame: Baseline, after 4 weeks and after 8 weeks.]
2. Change in serum creatinine.
   It will be assessed by the analysis of the plasma content by spectrophotometry.

   [Time Frame: Baseline, after 4 weeks and after 8 weeks.]

Secondary Outcome Measure:

3. Functional capacity.

It will be assessed by the six-minute walk test (6MWT).

[Time Frame: Baseline and after 8 weeks.]

4. Muscle strength of lower limbs.
   It will be evaluated by the sit-and-stand test with 10 repetitions.

   [Time Frame: Baseline and after 8 weeks.]

5. Muscle strength of quadriceps.
   It will be evaluated by dynamometry per load cell.

   [Time Frame: Evaluated: baseline and after 8 weeks.]

6. Quality of life evaluation.
   It will be assessed by the application of the EuroQoL-5D questionnaire.

   [Time Frame: Baseline and after 8 weeks.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	80 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Patients with CKF on HD for a period ≥ 3 months;
- Kt/V ≥ 1.2 or URR ≥ 65%
- Age between 18 and 80 years old;
- Functional capacity ≥ 300 meters in the 6MWT.

Exclusion Criteria:

- Cognitive dysfunction that prevents the performance of evaluations, as well as an inability to understand and sign the informed consent form;
- Intolerance to the electrostimulator and/or alteration of skin sensitivity;
- Patients with sequelae of stroke;
- Recent acute myocardial infarction (two months);
- Uncontrolled hypertension (SBP> 230 mmHg and DBP> 120 mmHg);
- Grade IV heart failure according to the New York Heart Association or decompensated;
- Unstable angina;
- Peripheral vascular changes in the lower limbs such as deep vein thrombosis;
- Disabling osteoarticular or musculoskeletal disease;
- Uncontrolled diabetes (blood glucose> 300mg/dL);
- Feverish state and/or active infectious disease.

Contacts/Locations

Central Contact Person:	Rodrigo DM Plentz, PhD Telephone: +55 5191131651 Email: roplentz@yahoo.com.br
Central Contact Backup:	
Study Officials:	Rodrigo DM Plentz, PhD Study Principal Investigator

Federal University of Health Sciences of Porto Alegre

Locations:

IPDSharing

Plan to Share IPD: No

References

Citations:

Links:

Available IPD/Information: