

# Effects of the BodStim TM Bioelectric Exercise Suit on Serum Klotho Levels and Exercise Capacity in Healthy Population



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ClinicalTrials.gov Identifier: NCTXXXXXX TBD

Recruitment Status : Enrollment launching 1H 2023

First Posted : January 20th, 2023

Last Update Posted : January 20th, 2023

## **Sponsor:**

Leonhardt Ventures LLC and Lionheart Health, Inc.

Information provided by (Responsible Party):  
Leonhardt Ventures LLC, Dr. Leslie Miller, Chief Medical Officer

- **Study Details**

## Study Description

Brief Summary:

**BodStim TM bioelectric stimulation exercise** program in serum **Klotho** levels and exercise capacity

Condition or disease	Intervention/treatment	Phase
Healthy Population	Other: BodStim TM bioelectric stimulation augmented Muscle based <b>exercise</b> Other: BodStim bioelectric stimulation Aerobic based <b>exercise</b>	Not Applicable

### Detailed Description:

This study aims to analyze the effects of BodStim TM bioelectric stimulation augmented exercise in serum Klotho level and exercise (muscle and aerobic based) capacity changes in healthy population

### Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	100 participants
Allocation:	Non Randomized

Intervention Model:	2 groups - muscle or aerobic exercise - patient choice
Intervention Model Description:	BodStim TM bioelectric contraction and non-contraction stimulation augmented exercise
Masking:	
Primary Purpose:	To assess serum klotho level and exercise capacity (muscle and aerobic) changes
Official Title:	Effects of BodStim TM bioelectric stimulation augmented exercise on Serum <b>Klotho</b> Levels and Exercise Capacity in Healthy Population: Response and Adaptation
Actual Study Start Date :	March 1, 2023
Actual Primary Completion Date :	TBD
Actual Study Completion Date :	TBD

## Arms and Interventions

Arm	Intervention/treatment
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<p>Experimental: Muscle based exercise BodStim TM bioelectric stimulation augmentation</p> <p><b>Effects of BodStim TM stimulation augmented muscle lifting based exercise</b></p>	<p><b>MUSCLE LIFTING BASED EXERCISE ARM</b> - 20 minutes of contraction stimulation and 40 minutes of klotho and follstatin expression bioelectric stimulation below contractile level to equal 1 of electrical stimulation 2X a week for 12 weeks or 24 treatments total combined with muscle lifting based exercise of choice</p>
<p>Experimental: Aerobic based exercise BodStim TM bioelectric stimulation augmentation</p> <p>Effects of BodStim TM stimulation augmented aerobic based exercise</p>	<p><b>AEROBIC BASED EXERCISE ARM</b> - 20 minutes of contraction stimulation and 40 minutes of klotho and follstatin expression bioelectric stimulation below contractile level to equal 1 of electrical stimulation 2X a week for 12 weeks or 24 treatments total combined with aerobic based exercise of choice</p>

## Outcome Measures

### Primary Outcome Measure :

- 1 Change in serum **Klotho** levels [ Time Frame: Baseline and at 12 weeks]Change from baseline to 12 weeks after BodStim TM augmented exercise

### Secondary Outcome Measures :

- 1 **Change in Exercise Capacity Aerobic** For this test all people will perform an aerobic **exercise** test on treadmill for 6 minutes attempting maximum distance in walk distance at baseline and at

12 weeks. If a treadmill is not available they may perform jumping jacks.

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**2 Change in Weight** For this test all people will measure their weight at baseline and at 12 weeks.

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**4 Change in Muscle Lifting Capacity**

For this test all people will perform the same muscle based exercise at baseline and at 12 weeks and will record the change in number of repetitions until having to stop and the maximum weight lift achievable. This can be dumbbell lifts, leg lifts, situps with a weight in hands, bench pressing, pull ups or any other muscle lifting exercise as long as baseline and 12 weeks tests are matched.

## Eligibility Criteria

## Information from the National Library of Medicine



*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).*

Ages Eligible for Study:	18 Years to 85 Years (Adult)
Sexes Eligible for Study:	Male
Accepts Healthy Volunteers:	Yes

**Criteria**

**Inclusion Criteria:**

- healthy people between 20 and 85 years old

**Exclusion Criteria:**

- acute and chronic disease
- Smokers
- pacemaker patients
- heart failure and heart disease patients
- Diabetes patients
- Kidney failure patients
- Cancer patients
- Severe muscle trophy patients
- Patients with non-healing wounds
- Patients unable to exercise

**Contacts and Locations**

TBD

**Information from the National Library of Medicine**



*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCTXXXXXX TBD***

#### **Locations**

#### **Sponsors and Collaborators**

BodStim TM by BioLeonhardt Whole Body a Leonhardt Ventures LLC Company and Lionheart Health, Inc.

#### **Investigators**

Principal Investigator:	TBD		
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#### **More Information**

Responsible Party:	
ClinicalTrials.gov Identifier:	<u>NCTXXXXXX</u> TBD

Other Study ID Numbers:	TBD
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Keywords provide

**Klotho**  
**Exercise**  
Electrical Muscle Stimulation