Bioelectrical Stimulation + Stem Cell Composition Mix for Erectile Dysfunction

Verified Date: July 2016 | **Sponsor:** MyoStim ED (A Leonhardt Ventures Co.)

Collaborator: Harbor UCLA LABioMed | **Status:** Phase II Interventional Study

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1. STUDY OVERVIEW & PURPOSE

This clinical investigation focuses on the synergy between **Bioelectric Stimulation** and **Autologous Fat-Derived Stem Cell Mix** for the treatment of moderate to severe Erectile Dysfunction (ED).

- **Mechanism of Action:** Controlled bioelectric signaling to trigger the release of specific regenerative proteins.
- **Target Proteins:** SDF-1, Follistatin, IGF-1, HGF, EGF, eNOS, VEGF, Activin A+B, and Tropoelastin.
- **Primary Goal:** To assess the safety, efficacy, and long-term durability of this combination therapy in patients who are refractory to standard treatments.

2. STUDY DESIGN & METHODOLOGY

- **Study Type:** Interventional (Clinical Trial)
- **Phase:** Phase 2
- **Design:** Randomized, Crossover Assignment, Open Label.
- **Estimated Enrollment:** 30 Male participants.
- **Intervention Model:**
    - **Active Group:** Bioelectric stimulation via proprietary bandage wrap + stem cell mix infusion into the penis.
    - **Control Group:** No initial intervention (Monitoring period).
- **Procedure:** Liposuction for retrieval of patient's own (autologous) stem cells from adipose tissue, followed by localized bioelectric delivery.

3. ELIGIBILITY CRITERIA

Ages Eligible for Study: 40 Years to 70 Years (Adult, Senior)

- **Inclusion Criteria:**
    - Males suffering from moderate to severe erectile dysfunction.
    - Must be in a potentially active sexual relationship.
- **Exclusion Criteria:**

- Severe diabetic neuropathy, Charcot joints, or diabetic ulcers.
- Major penile fibrosis or severe Peyronie's disease.
- Severe primary large vessel ED (PSV < 15cm/s) or venous leakage (EDV > 10cm/s).
- History of systemic chemotherapy or radiotherapy.

4. OUTCOME MEASURES

- **Primary Outcome:** Assessment of Adverse Events (AE) to determine safety and tolerability.
- **Time Frame:** 1 Year follow-up.
- **Secondary Outcome:** Evaluation of erectile function recovery using standardized clinical indices.

5. CONTACTS & INVESTIGATORS

- **Responsible Party:** Howard Leonhardt, Executive Chairman, MyoStim ED.
- **Clinical Facility:** Harbor UCLA LABioMed.
- **Official Resource Links:**
  - **NLM/MedlinePlus:** Erectile Dysfunction Topics
  - **Clinical Trials Registry:** ClinicalTrials.gov (Search Identifier: BioStim ED)