August, 2024

ORTHOSTIM CLINICAL PROTOCOL FOR KNEE OSTEOARTHRITIS USING BIOLECTRIC STIMULATION

Study Description:

This is a consecutive series pilot study to evaluate the safety and feasibility of OrthoStim treatment regimen to relieve the pain and disability of significant osteoarthritis of the knee.

Target Number Enrolled:

10

PROTOCOL:

Inclusion Criteria:

Age 40-80 yrs of age, BMI < 40, significant knee osteoarthritis by imaging with plain X-Ray within 3 months of treatment, willing to be present for the required treatment/study visits.

Exclusion Criteria:

Patients who have a planned arthroscopic procedure on the knee intended for treatment of osteoarthritis in the next 3 months, history of bleeding disorder, individuals with diminished decision-making capacity, current Smoking or use of other tobacco products, pregnancy or current breast feeding for females

Screening/Study Enrollment:

Any subject with qualifying osteoarthritis pain and reduced mobility who meet all the Inclusion and none of the Exclusion criteria, will be eligible for participation. Each potential subject will have a brief history and examination performed by the Investigator or designee, and if acceptable, will be provided with an overview of the study and offered an opportunity to review the Consent Form. If they choose to participate, and sign the Consent form, they will be enrolled in the study.

Bioelectric Stimulator: HTM stimulator strength training (400ms and 80hz, for 15 minutes, duty cycle ratio 1:2, and active muscle contraction, electrodes on the quadriceps muscle) and Klotho (400ms and 20hz for 45 minutes, electrodes on the side of the knee, and quadriceps muscle). Treatment Duration: 12 weeks, frequency of Treatments: Twice/week, total treatments: 24. Surface electrodes placed on the both sides of the knee, and on both sides of the quadriceps muscle above the treated knee.

Study End Points:

Klotho Protein: In the beginning of the study, immediately after 24 sessions, 24 and 48 hours after the last session, the klotho protein will be quantified

Pain Assessment: All eligible subjects will complete a baseline questionnaire to evaluate the amount of pain and disability before starting treatment. This survey will be repeated at the end of either the 8 or 12 week treatment period, and then at 1 and 3 months of follow up post treatment.

Range of Motion Assessment: Before and at the end of the 12 week treatment.

Muscle Strength: Before and at the end of the 12 week treatment.

Walk Speed: Before and at the end of the 12 week treatment.

Patient Knee Symptoms: Patient knee symptoms will be evaluated using the McMaster University and Western Ontario Universities Osteoarthritis Index (WOMAC). The WOMAC questionnaire will be measured at the beginning, at the end of the 8 12 week treatment.

TOTAL VALUE OF THE WORK PLAN (COSTING+CAPITAL+REFUNDS): US$ 12.446,22

Half of the amount shall be transferred at the beginning of the study, with the remainder to be paid upon the presentation of the final results.

Juiz de Fora 07/08/2024

Principal Investigator