Theranova, LLC

CLINICAL STUDY PROTOCOL – TNV-0514-WVD; CRD-09-1105

NCT03688282

Wearable Vibration Device to Prevent Bone Loss in Postmenopausal Women – Aim 2

April 17, 2019

Protocol Summary

Title	Wearable Vibration Device to Prevent Bone Loss in Postmenopausal Women– Aim 2
Sponsor	Theranova, LLC
Device	Wearable Vibration Device (WVD)
Background and Rationale	An emerging alternative to pharmacological interventions for osteoporosis is whole-body vibration (WBV). The wearable vibration device (WVD) aims to consistently deliver vibrations directly to the hip and spine and allowing use during many everyday activities. We propose that demonstrating higher rates of compliance and consistent delivery of optimal force with accelerometer-based force feedback will provide a superior alternative to WBV platforms and is plausibly more effective at preventing bone loss in postmenopausal women than vibration platforms in the home setting.
Objectives.	To demonstrate that postmenopausal women will: 1. Tolerate our device; 2. Receive consistently therapeutic levels of vibration; and 3. See changes in bone turnover.
Indications for Use/Patient Population	The device is to be worn by women who are postmenopausal to deliver vibration to the hips and spine to prevent bone loss. Subjects will be instructed to wear the device 30 minutes while walking or standing.
Trial Design	Single center prospective, non-randomized, unblinded, Non-Significant Risk (NSR) trial.
Study Population	Postmenopausal women
Number of Subjects	Up to 24
Number of Sites	1

Study Flow Outline Revised

Recruitment and Screening	Baseline Visit (Office Visit #1)					Intervention Assessment (Office Visit #2)				
Contact Interested Subjects Determine Eligibility Schedule Baseline Visit	Enrollment Consent	Fit Device Pre-Activity Blood Draw	30 Min Self-Selected Activity (WVD Motor Off)	Wait 30 Minutes Patient Questionnaires	Post Activity Blood Draw	Fit Device Pre-Activity Blood Draw	30 Min Self-Selected Activity (WVD Motor On)	Wait 30 Minutes Patient Questionnaires	Post Activity Blood Draw	Process Payment
	Internal Control Acute assessment of bone marker with no vibration stimulus.					**Treatment** Acute assessment of bone marker with 30 minute vibration.				

Study Procedures	***Screening Period (Ongoing)*** Potential subjects will answer screening questions via phone to determine eligibility. Women who qualify based on screening criteria will be scheduled for a baseline visit at the University of Nebraska Medical Center. Subjects with low or normal bone mass may be enrolled in the study. ***Study Period (1-2 weeks)*** The two week protocol consists of subjects: 1) visiting the clinic for a Wearable Vibration Device (WVD) pack fitting, wearing the device (motor off) for 30 minutes while standing or walking, and completing a pre-post activity blood draw, 2) visiting the clinic at the end of week one to measure acceleration, wear the device (motor on) for 30 minutes while standing or walking, and complete a pre-post activity blood draw.
Safety & Safety Monitoring	It is the responsibility of the investigator to report when an adverse event has occurred. Adverse event information will be collected throughout the study. Adverse Events (both expected and unexpected) will be recorded and reported appropriately.
Inclusion Criteria	1. Female 2. Last menstrual period at least one year and not more than six years. 3. 19 years of age and older. 4. BMD T-score at or above -2.5 at the total hip and L1-L4 spine skeletal sites as measured by DXA. 5. Ambulatory (can walk or stand without an assistive device for a minimum of 30 minutes). 6. Able to understand spoken and written English. 7. Capable and willing to follow all study-related procedures.

Exclusion Criteria	1. BMD T-score at or below -2.49 at the total hip and L1-L4 spine skeletal sites as measured by DXA. 2. A 10-year probability of hip fracture > 3% or major fracture or > 20% based on results of DXA using the FRAX tool (see attached). 3. Weight > 300 lbs. 4. Are currently taking or have taken bisphosphonates within the past 6 months, estrogen replacement therapy, or drugs affecting bone such as tamoxifen or aromatase inhibitors within the past 6 months. 5. Active cancer or cancer treatment. 6. Any change in Calcium or Vitamin D supplementation within the last 3 months. 7. Any change in exercise in the past 6 months. 8. Fracture~~s~~ or major surgery within the past 6 months. 9. Medical Implants (excluding dental implants). 10. Diagnosed with Paget's disease, heart disease, uncontrolled hypertension, renal disease, chronic fatigue syndrome, herniated disc, severe peripheral neuropathy, severe osteoarthritis. 11. Any bleeding disorder or treatment with a blood thinning medication within the last 2 years.
Statistical Analysis	This study is observational, is not statistically powered and no formal statistical analyses are planned. Data will be listed by subject; treatment number, and subject tolerability during treatment.