Long-Term Clinical Trial: Study Design Overview

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Rationale

Approximately 20 million Americans suffer from peripheral neuropathy (PN). Leading causes of PN include diabetes, unknown causes (idiopathic), and chemotherapy induced. The incidence increases with age.

Epidemiological evidence has linked PN to an increased risk of falling. There is a need for developing cost-effective interventions for improving mobility and balance to manage fall risk. Walkasins®, a lower limb sensory prosthesis that mimics lost foot pressure sensation with tactile sensory information around the lower leg, can address this need.

Recent research has demonstrated short-term improvements in gait and balance function in patients with PN using the Walkasins device. The walk2Wellness clinical trial investigates the long-term effects of wearing Walkasins on a continuous basis as a balance prosthesis for replacing lost foot pressure sensation.

Study Purpose

Investigate long-term effects of Walkasins use on clinical and patient-reported outcomes of gait function, balance confidence, physical activity, and social participation in patients with sensory peripheral neuropathy. Fall rates are monitored and compared to pre-study data.

Hypothesis

Patients using Walkasins every day, who receive tactile sensory balance information, will improve outcomes of gait function, balance confidence, physical activity, and social participation.

Study Design Summary

Assessment of Walkasins through a randomized cross-over study followed by pre- and post-assessments as well as periodic follow-ups. Multiple clinical sites across the country with up to 120 subjects participating. Assessment of subject response long-term (see figure below) vs. response in-clinic (after initial baseline assessment). Individual study results are not shared with subjects. Subjects may not begin any additional gait, balance intervention or treatment for the first ten weeks of the trial.

Outcome Measures

A set of reliable and valid measures of gait function will be used to assess patients for inclusion in the study and for assessing improvement over time. Outcomes captured include gait function, balance confidence, physical activity, social participation, quality of life, as well as tracking the falls.

1. Functional Gait Assessment (FGA) – The FGA is the recommend outcome measure for gait function and is used in predicting unexplained falls in community-dwelling older adults.
2. Walking Speed – A simple test often termed “the Sixth Vital Sign” is routinely done in rehabilitation and is highly predictive of long-term survival in older adults.
3. 4-stage Balance Test – Part of a test protocol for balance function that is recommended by the Centers for Disease Control (CDC).
4. Timed-Up-and-Go (TUG) – Part of a test protocol for balance function that is recommended by the Centers for Disease Control (CDC).

Several patient-reported outcomes are included to measure balance confidence, social participation and depression at multiple measurement points.

- PROMIS forms for pain and social participation
- Activities-specific Balance Confidence (ABC) scale
- Vestibular Activities of Daily Living (VADL)
- Patient Health Questionnaire (PHQ-9)

LEADING CAUSES OF PN

60% Diabetes
23% Idiopathic
10% Chemo-induced
15% Other
2% HIV/AIDS

Figure. Study design of walk2Wellness clinical trial for each of the sites.
Long-Term Clinical Trial: Study Status Update 10/2019
Interim study report as presented at ACRM 2019

An increase in the Functional Gait Assessment score with the use of Walkasins®, which may decrease the risk of falls.

- The Functional Gait Assessment is an excellent metric for classifying fall risk and predicting future falls and has been shown to be low in individuals with peripheral neuropathy.
- A history of falls has been linked to reduced confidence with mobility, decreased activity levels, ultimately contributing to decreased quality of life.

An increase in gait speed with the use of Walkasins.

- Gait speed typically declines with age and it declines faster in those with peripheral neuropathy.
- Slower gait speed is related to increased disability, need for fall prevention interventions, greater likelihood to be hospitalized, and reduced access to the community.

A reduction in fall rate and number of fallers with the use of Walkasins.

- According to the Centers for Disease Control and Prevention, more than 25% of individuals over the age of 65 fall each year, which results in total medical costs that exceed $50 billion each year.
- Individuals with peripheral neuropathy are up to 15 times more likely than healthy older adults to have a fall-related injury.
- Additionally, at 150 average use days with 42 subjects enrolled, 13 subjects have fallen post-enrollment with Walkasins use, compared to 23 subjects reporting falls during 180 days pre-study participation.

Caution: Prior to using this device, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, and precautions. Walkasins is an external lower limb sensory prosthesis intended to replace the nerve function used for detection and signaling of foot pressure sensation. Walkasins is indicated for patients with lower limb sensory peripheral neuropathy who present with gait and balance impairments. Walkasins is indicated for patients who can feel the tactile stimuli from the Leg Unit on the lower leg. This device is contraindicated for patients with untreated lymphedema; untreated lesion of any kind, swelling, infection, inflamed area of skin or eruptions of general medicine, 5, 805-812, doi:10.2147/JGM.S32651.