

## **Randomized Clinical Trial of Migraine Medications in Treatment of Tinnitus**

Tinnitus is the perception of sound in the absence of external stimuli. It is a debilitating condition that affects 12-17% of the population or 36-50 million Americans, of which 2 to 3 million individuals are estimated to be disabled by tinnitus. Tinnitus is also the number one disability among veterans and nearly 1.5 million veterans are currently receiving disability benefits for it for a yearly cost of over \$1.3 billion. In spite of the large economic and societal impact of tinnitus, currently there is no FDA-approved medication to treat this condition. Emerging evidence has been shown that there is a link between migraine and peripheral/central auditory dysfunction (i.e., tinnitus) with shared common pathophysiologic characteristics. This led us toward our innovative approach for the treatment of tinnitus by the means of our newly developed combination of migraine medications. The first aim of this study is to perform a randomized, double-blinded, placebo-controlled clinical trial to evaluate the effectiveness of nortriptyline-topiramate stepwise regimen in the treatment of tinnitus. This step-wise regimen consists of an algorithm of escalating doses of nortriptyline plus topiramate, which are commonly used drugs for the treatment of migraine but have not been verified for tinnitus in a clinical trial setting. We have observed the potential effectiveness of these medications in our uncontrolled retrospective data. We also aim to evaluate the effect of nortriptyline-topiramate combination on concomitant symptoms of tinnitus and quality of life in subjects with tinnitus. This aim will focus on providing a comprehensive assessment of the treatment with nortriptyline-topiramate combination and further elucidate on the potential global improvement subjects may experience with this regimen in comparison to a placebo. Finally, we will also elucidate the most effective dosage of nortriptyline-topiramate combination with the least side effects in the treatment of tinnitus. Accomplishment of these aims will provide a pilot assessment of the effectiveness of nortriptyline-topiramate combination in the treatment of tinnitus and their side effect profile.