Clinical Trial of Acamprosate for Tinnitus

William Hal Martin, Ph.D., and Yong-Bing Shi, M.D., Ph.D.,
Oregon Hearing Research Center, Oregon Health & Science University

Medical treatments for tinnitus have historically been difficult to evaluate. This is due to the extremely complex nature of tinnitus, diversity of tinnitus causes and lack of understanding about underlying mechanisms. Limited measurement tools and the challenges in the lives of those who suffer from tinnitus contribute to evaluation difficulties. The American Tinnitus Association is co-funding a clinical trial of a medication called acamprosate (brand name, Campral®) at the Oregon Health & Science University (OHSU) in Portland, Ore. Acamprosate was developed to help recovering alcoholics abstain from drinking by modifying the balance between excitatory (when nerves activate other nerves) and inhibitory (when nerves prevent others from activating) chemicals produced by the brain. It is possible that an imbalance in the hearing centers of the brain (not related to alcoholism) may be one cause of tinnitus. A pilot study in Brazil suggested that acamprosate might be helpful for some types of tinnitus.1

Bringing Participants on Board

The three-year OHSU study began in January 2008 and has been a massive endeavor. So far we have processed over 2,000 contacts from tinnitus sufferers interested in being in the study. Of those, 596 individuals went through screening evaluations and 234 have met the very strict inclusion criteria to participate in the study. Most of those have enrolled in Phase I of the trial.

Phases I, II and III

Phase I is an open-label trial (both the researchers and participants know the identity of the treatment) during which all participants take acamprosate for six weeks. Those who respond positively to the medication may continue into an extended Phase II of the study. We release from the study those who did not have a positive response to the acamprosate in Phase I or asked to be released for other reasons, such as side effects, logistics or time constraints.

During this second phase, everyone receives acamprosate for part of the time and a placebo for part of the time, without knowing which they are taking at any given time. This experimental design is very important because it recognizes that no treatment should be expected to work for everyone with tinnitus. It separates non-responders from potential true responders early in the study and allows us to focus resources and research efforts on those most likely to benefit from the treatment.

We are continuing to enroll participants in Phase I and hope to enroll about 300 people in all. We have begun Phase II as well. During Phase III of the study, we will look back at those who did and did not respond positively to acamprosate. (This can include a decrease in the perceived loudness of their tinnitus, or an improvement in their overall quality of life.) During this review process, we identify factors (tinnitus pitch, loudness, duration, other medical issues, etc.) about those groups that will help us predict who should or should not benefit from acamprosate treatment. We believe that this will help us understand the role of the brain in tinnitus and help us develop more effective treatments in the future.

Recognition for Innovative Design

The tinnitus research community recognizes this study for its importance on three levels. First, everyone is interested in knowing if medications like acamprosate can be helpful to those with tinnitus. Second, we are all interested in the role of the brain in tinnitus and this experiment allows us to change brain chemistry in a very interesting way. Finally, and perhaps most importantly, this is the first time anyone has applied this type of strict experimental design to studying interventions for tinnitus. The design may prove to be the standard by which the research community evaluates all future medical therapies.

William Hal Martin, Ph.D., is Professor of Otolaryngology/Head and Neck Surgery and Professor of Public Health & Preventive Medicine at the Oregon Health & Science University in Portland, Ore. He directs four programs within the Oregon Hearing Research Center: the OHSU Tinnitus Clinic, Tinnitus Research Program, Intraoperative Neurophysiological Monitoring Services and Dangerous Decibels® Noise

continued on page 25
annoying, your dentist could refer you to someone who can provide you with a temporary “fix” – a plastic insert to wear in your mouth at night that prevents teeth grinding.

Q  I hear a lot of comments about a cure for tinnitus but I do not hear any comments as to how such a cure might be found. In your opinion, is a cure a realistic possibility, and if so, how will it come about?

A  Yes, I think a cure is possible, at least for certain kinds of tinnitus. As you well know, as hearing declines, tinnitus increases; it’s something of a see-saw effect. Now given that dynamic, if we can improve hearing it is my guess that tinnitus will decrease.

How do we increase hearing? Hopefully we’ll do it with stem cells. We can harvest these versatile cells from the person’s own nasopharynx (uppermost part of the pharynx, extending from the base of the skull to the upper surface of the soft palate) so that there is no or little chance for rejection. In my opinion, work with stem cells has the possibility of enhancing recovery from all manner of health problems.

Can a Simple Kiss on the Ear Cause Auditory Problems?

continued from page 11

delicate cilia (ear hair cells) leading to SNHL, tinnitus and hyperacusis.

Treatment for REKS has not yet been successful, but prevention is a must. A light kiss to a child’s ear produces a surprisingly rapid and intense ear canal vacuum. An infant cannot say, “Mommy, I can’t hear now.” Let us avoid preventable tragedies like this. Kiss, and kiss away, but please avoid that ear canal.

Dr. Levi A. Reiter is Professor of Audiology and the audiology program head at Hofstra University’s Department of Speech-Language-Hearing Sciences. He teaches courses in diagnostic audiology, anatomy and physiology, psychoacoustics, deafness and electrophysiology. He is also on the faculty of the Long Island Audiology Consortium and maintains an active audiology practice in Brooklyn, N.Y. The grandfather of 20 is a published rapper and enjoys promoting the audiology profession with songs like, “Say Whut?”

3Reiter, 2008.
4Smaka, C. The kiss that caused hearing loss, or Reiter’s Ear-Kiss Syndrome (REKS). Audiologyonline. 2008 July 28.
5Reiter, 2009.

Clinical Trial of Acamprosate for Tinnitus

continued from page 21

Induced Hearing Loss and Tinnitus Prevention Program. Martin also serves as the Research Scientist in Residence at the Oregon Museum of Science and Industry (OMSI) in Portland.

Yong-Bing Shi, M.D., Ph.D., is Assistant Professor of Otolaryngology/Head and Neck Surgery at the Oregon Health & Science University. He examines and treats patients with tinnitus and hearing problems, as well as voice and swallowing disorders. He also serves as the medical director of the OHSU Tinnitus Clinic and the Northwest Center for Voice and Swallowing. In addition, Shi monitors brain, nerve and spinal cord function during surgical procedures in which those structures may be injured by the procedure.