

Phase 3 Drug Study for Noise induced Hearing Loss Cure

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Two and a half years ago Hearing International discussed various homeopathic medicine treatments for [In Part V of this discussion](#), we referenced the impressive a research headed by [Dr. Kathleen Campbell](#), audiologist and researcher at Southern Illinois University. A prolific researcher, whose team at Southern Illinois University has discovered that antioxidants can reduce hearing loss created by aminoglycoside ototoxicity and reduce or eliminate the effects of noise induced hearing loss.

At the beginning [Phase 2 of US Food and Drug Administration \(FDA \) clinical trials](#) in the use of [D-Methionine \(D-Met\)](#), Dr. Campbell indicated that the goal of their team was to be sure that when they “came out with a statement, it is scientifically correct and well documented.” In an interview with [Beck \(2013\)](#), she underscored that point as she presented that there are thousands of supplements, vitamins and other “cures” available from the Internet and other sources that have very suspicious claims as to their benefit.

The Science Behind the Research

In our last discussion of this topic, [Mandal \(2013\)](#) described the science involved as related to oxygen in that “all living organisms use oxygen to metabolize and use the dietary nutrients in order to produce energy for survival. ([Click here for an antioxidant video](#)). Oxygen is a highly reactive atom that is capable of becoming part of potentially damaging molecules commonly called “free radicals.” If not familiar with the relationship of oxidation of molecules into free radicals and how antioxidants can affect metabolism, a super discussion is available at [Healthy Check \(2015\)](#). Basically, due to metabolism and other factors, such as noise exposure the auditory system, unstable molecules are created in the cellular structure by “oxidation”. In the auditory system, theory has it that these unstable, oxidized molecules or “free radicals” attack other portions of the cellular structure to steal electrons to become stable again. This stealing of electrons from other molecules causes a less stable cellular structure and, in the auditory system, contributes to the loss of hearing sensitivity. This process also is also thought to be a cause of other disorders such as heart disease, cancer, aging and many other conditions.

A stabilizing factor for these unstable molecules is antioxidants. Antioxidants serve as a stabilizing agent by reversing the oxidation process as they donate their atomic structure to the oxidized molecule (free radical). These antioxidants are a source of controlling these free radicals as they have extra electrons that can turn the free radical molecule back into a healthy molecule by donating one of its electrons to the free radical. This process does not turn the antioxidant into a free radical as they have electrons to spare and are not disturbed by this structural modification. Some antioxidants are created by the body naturally while other are obtained from the food we eat. Vitamin supplements often include antioxidant vitamins such as C and E to offset these molecular oxidation issues controlling the free radicals but can also be found in fruits, vegetables, wine,

chocolate, and many other foods that we eat everyday. D-Met, the substance that is being tested as a drug to replenish these electrons to the free radicals within the auditory system is an antioxidant that has been scientifically proven to reduce the oxidation of molecules (or creation of free radicals) in the auditory system and the chain reaction that causes damage to hearing.

Proven to Date

Dr. Campbell's team, collaborated by other research teams, have now proven that:

1. D-met protects against radiation-induced oral mucositis, [cisplatin-induced](#) ototoxicity and other cisplatin side effects, aminoglycoside-induced hearing loss, and noise-induced hearing loss.
2. Phase 2 clinical trials for [radiation-induced oral mucositis](#) and [cisplatin-induced hearing loss](#) have shown significant protection with oral D-met administration.
3. D-met also provides partial protection from aminoglycoside-induced hearing loss with no antimicrobial interference in animal studies.
4. D-met protects against noise-induced hearing loss if given before, during or even when first started up to 7 hours after noise-cessation. It also protects if only given prior to the noise, even if stopped one day prior to the noise exposure.

The New Research

In August 2015, the research moved on to [Phase 3 of the FDA clinical trial](#). Since the use of D-Methionine has been proven to be of benefit for noise induced hearing loss, the Phase 3 of the FDA process will establish the safety and the dosage of the drug for use in humans. Dr. Campbell's team has now secured funding from the US Department of Defense and has begun Phase 3 of the FDA clinical trial at Fort Jackson where volunteer subjects that are Army soldiers attending the [Drill Sergeants Course](#) are participating in the study. As part of their training over 11 days at the rifle range as the drill sergeant candidates, each will fire an M16 at least 500 times. The M16 is one of the U.S. Army's quieter weapons, but that isn't saying much. For the shooter, shots from the rifle, even if muffled by Army-issue earplugs, register above the noise level hearing experts consider safe. As audiologists know, the M-16 puts out an impulse noise of over 154 dB (A) well above the levels that will cause damage to the auditory system and another variable is the number of these exposures per day. Most audiologists realize that a day at the rifle range will cause a significant temporary threshold shift and some permanent auditory damage, making this environment perfect for this phase 3 trial of the D-Methionine therapy. After searching for 10 years, she found the Army where noise is part of everyday life, especially when spending lots of time at the rifle range. She and her two research nurses use a former break room at the Drill Sergeant Academy to administer hearing evaluations and necessary questionnaires to discuss about potential side effects, and administer the D-Met during Chow time.

According to the Army (2015), Staff Sgt. Tyler Durden of the Joint Readiness Training Center at Fort Polk, Louisiana, already experiences tinnitus, a ringing in the ears caused by hearing damage. He was a ready volunteer for the trials because "this is a huge opportunity to make things better for everybody" subject to hearing loss. He slugged back a dose of the orangish liquid, whose taste he said reminded him and other waggish Soldiers of the excretions of an animal none of them is likely to have encountered. Even so, Sgt. Durden did not request the proffered water, juice or peppermints nurses had brought with them to alleviate the taste of the medicine.

Since the study is [randomized and double blind](#) and the data will go to Yale for analysis, even Dr. Campbell does not know who gets the drug and who gets the placebo. This is a seminal moment for the cure of noise induced hearing loss. If it works, there will be substantially less hearing loss due to noise exposure... *what will audiologists do!*

References

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