APPROVED JUNE 25, 2018 INTEGREVIEW IRB

Hearing Loss Study



Alamo ENT AssociatesJeffrey S Rosenbloom MD

Innovative research to potentially restore hearing damaged by noise or acute loss is being investigated by Dr. Rosenbloom.

This investigational study involves injecting medicine into the middle ear. The drug is absorbed into the inner ear. The purpose is to potentially restore the damaged cells that are responsible for hearing.

You must have a previous hearing test that demonstrates stable hearing loss for at least 6 months or longer and be between the ages of 18-65. Therefore, you would need to have been tested in our office, another physician's office or an audiologist.

If you are interested, please inquire or call (210) 545-0404.

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Hearing Loss Affects Over 1 Billion People Worldwide

Worldwide, an estimated 1.1 billion people are at risk for hearing loss due to exposure to damaging levels of sound. Sensorineural Hearing Loss (SNHL) is one of the most common diseases, accounting for about 90% of all hearing loss. SNHL hearing loss occurs when the inner ear is damaged, is usually irreversible and managed with hearing aids or cochlear implants.

What if a simple, locally-delivered drug could enable our body to regenerate and heal itself?

A research study with an investigational drug called FX-322 could potentially restore the hair cells of the inner ear and improve hearing!

To participate in this research study:

- You must be a male or female adult, 18 to 65 years.
- Have an established diagnosis of stable SNHL by standard hearing tests.

How does FX-322 Work?

Frequency Therapeutics, Inc. is developing FX-322 for the treatment of hearing loss. FX-322 is a combination of the two different medications. The drug product changes to a gel at body temperature (e.g. in the middle ear) in order to increase the likelihood of delivering drug to the inner ear where the hair cells are located. FX-322 is given by an injection through your eardrum into the middle ear where the active ingredients are absorbed into the inner ear. Injections through the eardrum are commonly performed in the offices of otolaryngologists and are well tolerated by patients.

Who is paying for this study?

The study is being funded by Frequency Therapeutics, Inc., a company dedicated to eradicating hearing loss. There will be no cost to your insurance company to be in this study. Frequency Therapeutics, Inc. will pay for the costs of the study drug, study-related tests and procedures and study visits. You will also be reimbursed for your travel to and from the Worldwide Clinical Trials (WCT) Phase 1 Unit located at 2455 NE Interstate 410 Loop #150, San Antonio, TX 78217.

CONTACT INFORMATION

If you want any further information concerning this study, you can contact the Principal study doctor at: (210) 545-0404.