Could the FX 322 drug cure hearing loss?

The science, the trials and the reality

Overview of FX 322 | How does FX 322 work? | What are stem cells? | The science behind FX 322 | The FX 322 trials | Is a cure possible for hearing loss?

Last Hearing Aid UK Update: 14/08/2026

March 2023: This article was originally published in June, 2022. It has recently been updated with new information and a complimentary video, both found at the bottom of the article.

Other 2025 updates include: Frequency Therapeutics has shut down, FX-322 and FX-345 will not continue development, and has no new trials, acquisitions, or investor interest.

If you've been following news about hearing loss cures, you've probably come across FX-322. It generated significant excitement in the hearing loss community, with many people postponing hearing aid decisions in hope of a cure.

Unfortunately, as this article explains, those hopes haven't materialised - but understanding why is important for anyone with hearing loss.

A new drug, the FX 322, is said to reverse hearing loss

Research was undertaken by Frequency Therapeutics*, a new drug that is injected into your ear and designed to promote stem cell growth. This will regenerate and develop hair-like stereocilia cells, which are said to reverse hearing loss. Below, we look at the science, the trials, and what ultimately happened.

How does it work?

The drug, named FX-322, is an injection that is said to work by stimulating the dormant stem cells inside your ear to grow new healthy auditory cells that send sounds to your brain for you to process and understand. It is said to be delivered into the middle ear and absorbed by the inner ear.

What are stem cells?

Throughout your body, you have stem cells that are incomplete and usually have the ability to develop into any form of tissue.

This particular drug encourages them to grow into stereocilia, which are hair-like cells in your ears that detect sound. Hearing loss occurs when these hair cells are irreversibly damaged, as they cannot repair themselves.

Today, hearing aids remain the most successful way to amplify sound and support hearing. These early studies hope to restore sensorineural hearing loss (SNHL).
Sensorineural hearing loss is the most common type of loss caused by ageing, genetics and prolonged exposure to loud sounds.

However, it is one thing to grow hair cells; getting them to work is another thing entirely. This is the crucial bit that often gets overlooked in headlines about hearing loss cures.

Even if you could regenerate hair cells, they need to connect properly to the auditory nerve and function as part of a complex system.

It's rather like replacing a component in a computer - installing it is one thing, making it communicate with everything else is considerably more challenging.

Simplifying the science

The FX 322 contains drugs that early studies indicate help aid new hair cell formation. These are called progenitor cells, which are unable to evolve into any body tissue. Instead, they are usually more inclined to develop into cells near where they are found in the body.

So the progenitor cells in the ear will more than likely turn into tiny hearing cells. In short, this drug is designed to assist in helping molecules activate these cells to regrow the lost sensory cells. These cells are needed to filter and tune sounds.

FX 322 drug testing and trials

At the time, the research was still in its infancy, with a lot of 'ifs', 'buts', and various hoops to jump through before this drug could be signed off for larger-scale human trials.

There were only small trials (around five clinical studies) so far, with researchers stating that this new drug may help hearing, such as the clarification of sound, speech perception, and understanding, with hair cell regeneration.

With each study undertaken, the scientists behind this research added to their overall understanding of the FX 322 drug, with some speech perception improvements, which were published in *Otology & Neurotology.*

However, from our understanding of the studies that followed, the drug showed no signs of improvement when compared to the placebo, rendering the evidence inconclusive.

This is particularly telling. In clinical trials, if a drug can't perform better than a placebo, it suggests the treatment isn't working as hoped. The placebo effect itself can be quite powerful, which is why proper controlled trials are essential.

The FX 322 Drug

The reality of the trials

No hearing loss cure yet

A follow-up version of the drug, FX-345, was also in early development, but this too has now been permanently discontinued alongside FX-322. Frequency Therapeutics has since shifted its focus away from hearing loss research entirely.

Currently, there is no drug or treatment to repair the sensory system, and in reality, the full restoration of hearing is not just debatable but unlikely. This might sound discouraging, but it's important to be realistic.

Whilst research continues worldwide, including in UK universities, we're likely many years away from anything approaching a "cure" for most types of hearing loss.

Hearing aids remain the most successful and proven way to manage hearing loss for the foreseeable future, and today's technology is better than it has ever been.

What is clear is that the more we research the causes and ways to manage hearing loss, the more we understand it. However disappointing, trials are still a very important part of audiology research. Such research ultimately influences the evolution of hearing aid technology in the future. Making them better, more efficient, more personable, more powerful.

Whilst we wait for breakthroughs in regenerative medicine, hearing aid technology has advanced remarkably. Modern hearing aids can do things that would have seemed impossible a decade ago - from AI-powered noise reduction to direct streaming from any Bluetooth device.

The gap between "cured" hearing and well-managed hearing loss is narrower than many people think.

Latest update for FX 322 clinical drug trials

This clinical trial has been permanently discontinued following poor results, with no plans to reintroduce the program. The news has come as no shock, as there have been whispers of lacklustre developments from the start.

However, trials such as these are an important part of hearing loss research.

"This was a rigorous and well-designed study that provided us a clear outcome, though not the outcome we wanted. Given these disappointing results, we will cease further development of the company's drug candidates for hearing loss."

Statement by Dr Chris Loose, Frequency Therapeutics' Chief Scientific Officer**

Conclusion

If you're experiencing hearing loss and have been waiting for a cure before considering hearing aids, it's worth getting a hearing test to understand your options. The support available now can make a genuine difference to your daily life.

Failed trials like FX-322 are disappointing but valuable - they help researchers understand what doesn't work and inform future approaches.

**** FX-322 drug developed by Frequency Therapeutics and the Massachusetts Institute of Technology in the U.S***