



A randomised controlled trial of STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss

Dear

'WELCOME to the STARFISH trial'.

Firstly, we would like to thank you for agreeing to take part in this trial run by the Birmingham Clinical Trials Unit (BCTU), as we appreciate this can be an anxious and distressing time for you.

Steroids are the best treatment that we have to try and improve hearing after a sudden inner ear hearing loss, which is known as a sudden sensorineural hearing loss (SSNHL). They are usually given by mouth or directly into the ear by three injections through the ear drum.

The aim of this trial is to work out whether steroids taken by mouth for seven days, three steroid injections into the ear or a combination of these two treatments is best at improving hearing after SSNHL.

You will have received and read the STARFISH Participant Information Sheet. We have included further information in this pack on the treatment/s that you will be receiving.

If you have kindly agreed to take part in the home hearing tests, these can be performed on a smartphone, tablet or desktop computer. We have included a pair of earphones and a wallet-sized card that contains your unique participant identifier number; you will need this when you log in to perform the home hearing tests.

You will receive weekly text messages to help remind you to perform the home hearing tests. These will only continue for 12 weeks, which is the length of the trial.

We would also appreciate it if you could complete the Participant Questionnaire Booklets at the start of the study, and then again at six and twelve weeks later when you come to the hospital for your scheduled clinic visits to test your hearing. We can help you fill the questionnaires in if needed.

If you cannot make your scheduled appointments, please let the STARFISH trial team treating you know in advance.

If you have any further questions or want to discuss any concerns, please do not hesitate to contact a member of the STARFISH trial team who will be more than happy to talk with you.

Contact Tel No.:

The results of the trial will be shared with the public via:



STARFISH Facebook group - @StarfishTrial



STARFISH Twitter page - @STARFISH_trial



>Insert web link<

Pack contents:

- ❖ STARFISH Participant Information Leaflet (oral steroid)
- ❖ STARFISH Participant Information Leaflet (IT steroid)
- ❖ STARFISH Home Hearing Test User Guide
- ❖ STARFISH Participant Card
- ❖ Earphones
- ❖ Pen

Again, thank you for your contribution into this important trial, which should help work out the best way of improving hearing in patients that experience sudden sensorineural hearing loss in the future.

Sincerely,

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