



December 2024

STARFISH Newsletter

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

Message from the CIs

"We would like to thank all those who have helped make the STARFISH trial a success in 2024. The last year has seen large numbers of STARFISH associate PIs registering with the NIHR scheme, beating any previous ENT trial, and we have taken the study into new areas, continuing to open hospital sites across the UK each month as we work towards our aim of 75. Recruitment has been slower than expected, but many sites have worked hard to design effective patient pathways to capture eligible patients as they come into the ENT service. We also recognise the effort teams have made to engage with GPs and other departments to improve patient care for those with SSNHL.

Going into 2025 STARFISH is in a strong position, having gained further funding to extend the study into 2026 and meet our recruitment target of 525 patients. We ask that in the New Year site investigators continue to engage with your teams, reminding them about the trial and bringing in any new nurses, audiologists or ENT trainees who can help deliver the study. We host remote meetings every few weeks to induct any new staff you have, and are always open to questions.

We hope you have a restful Christmas and look forward to working with you in the New Year.

Matt Smith and James Tysome

Co-Chief Investigators, STARFISH Trial'

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good news!

We can share the excellent news that the NIHR has confirmed an extension to the STARFISH trial.

The updated dates are as follows:

- ◆ New end of recruitment date: 30-Nov-2026
- ◆ New end of study date: 31-May-2027

The STARFISH protocol has now been published. It can be viewed on PLOS ONE [here](#).

Site Information



'Thank You!'

We would like to say a massive 'Thank You!' to all the site team members for your support and hard work enabling us to open 56 sites to date, along with a further 7 in set-up and 10 that have shown an expression of interest.

[Click here to view the list of sites on the STARFISH website.](#)

Recruitment Information

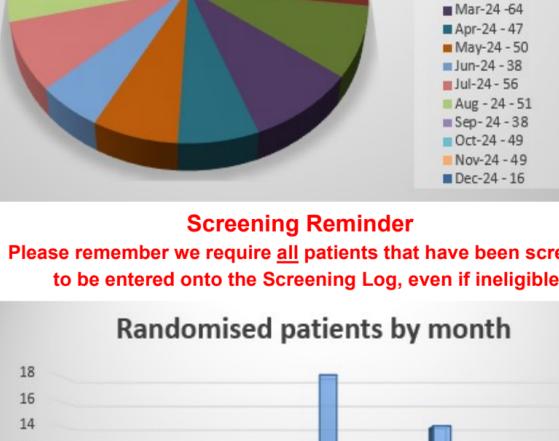
To date you have screened over 700 patients and recruited 132 into the STARFISH trial.

March 2024 was the best month since opening the trial for both screening and recruiting patients, with 65 screened and 18 recruited.

Congratulations to **UCLH** for being the top screening site with 116 patients.

Congratulations to **Addenbrooke's** for being the top recruiting site with 13 patients.

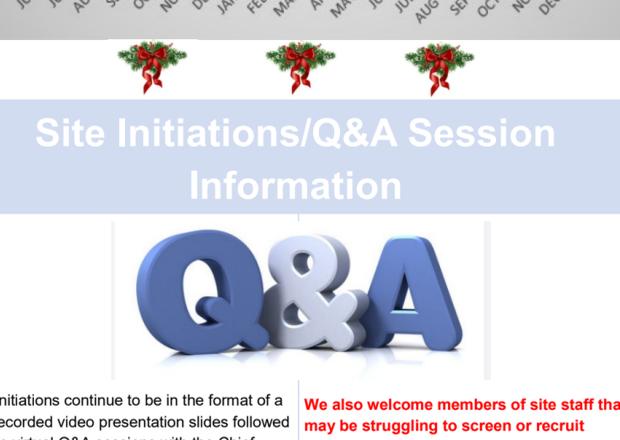
Screened patients by month



Screening Reminder

Please remember we require all patients that have been screened to be entered onto the Screening Log, even if ineligible.

Randomised patients by month



Site Initiations/Q&A Session Information

Q&A

Site initiations continue to be in the format of a pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigators and trials office team, hosted on Zoom. This is mandatory for the PI and Associate PI, although we recommend that anyone involved in research activities for the trial attends too.

Site staff can access the pre-recorded presentation online via YouTube or the trial website at their convenience.

You will be asked to self-certify that you have watched the pre-recorded video as evidence of trial training prior to joining a Q&A session.

We will also be asking you to register for the Q&A session you will be attending; please do not share the Zoom meeting link details team colleagues, as the registration details will provide us with a record of attendees for report writing purposes.

We also welcome members of site staff that may be struggling to screen or recruit patients, to re-attend a Q&A session to discuss steps that other sites may have taken to overcome any barriers they have experienced.

The live Q&A sessions are held regularly, so you can attend a session that suits you; we would encourage you to join together as a team where you can.

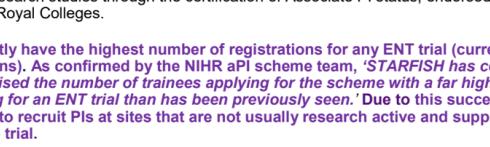
◆ 1st Monday of the month – 10:00-10:30

Please register [here](#).

◆ 3rd Tuesday of the month – 10:30-11:00

Please register [here](#).

NIHR Associate PI Scheme



We would like to remind you that the NIHR CRN Associate PI Scheme (Portfolio CPMS ID: 53517) is still open for registrations for the STARFISH trial.

The scheme is open to any healthcare professional willing to make a significant contribution to the conduct and delivery of a study at a local level over a period of at least six months and for STARFISH this opportunity is ideally suited to an ENT Specialist Trainee, though an Audiologist or nurse could also take on the role too.

Participating healthcare professionals receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.

We currently have the highest number of registrations for any ENT trial (currently 90+ registrations). As compared by the NIHR apli scheme team, 'STARFISH has completely revolutionised the number of trainees applying for the scheme with a far higher number registering for an ENT trial than has been previously seen.' Due to this success we have been able to recruit PIs at sites that are not usually research active and support them to deliver the trial.

We hope this will encourage participation of others at our STARFISH sites.

For more information visit: nhr.ac.uk/AssociatePIScheme

'Hints & Tips'



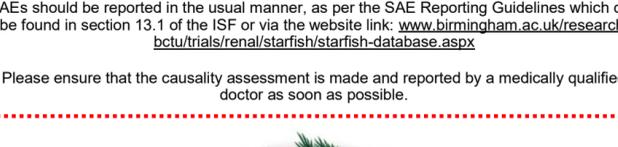
We have found that sites who are in a WhatsApp group together can stay in touch with members of staff about the STARFISH trial and any potential patients, hence aids recruitment.

CRF completion — common errors:

- ◆ Remember to complete 'Section 3 - Patient approach' at the end of the Screening Log for ALL screened patients.
- ◆ PIs remember to complete the 'Form Completed By & Sign Off' and 'Principal Investigator' sections of the Randomisation and Clinic Visit Forms. Both fields require PI sign off (located at the bottom of respective forms).
- ◆ Ensure that if a patient questionnaire booklet is not completed, it is marked as 'No' on the relevant Clinic Visit Form, this will stop repeat missing booklet reminders.
- ◆ Ensure that ALL Clinic Visit Forms are completed. If the visit did not occur still complete and add the reason why. **N.B.** if the Week 12 Clinic Visit Form is not completed this will impact on the patient payment being made.

CRF Returns

Thank you to all sites for your continued support in completing CRFs on the STARFISH database in a timely manner; the current return rate is over 90%!



We will soon be rolling out the optional HearX home hearing tests for consenting patients to take part in to define the trajectory of hearing recovery.



A unique participant ID will be issued at randomisation, followed by 12 weekly text message prompts sent to remind the patient to perform the tests.

More information to follow in 2025.



Christmas Closure & SAE Reporting

Birmingham Clinical Trials Unit (BCTU) and the University of Birmingham will be closed from 16:00, Friday 20th December 2024 until 08:00, Thursday 2nd January 2025

The STARFISH online database (<https://starfish.bctu.bham.ac.uk/>) will be available over the Christmas period

The STARFISH mailbox (STARFISH@trials.bham.ac.uk) will be monitored periodically over the Christmas period; if your query is urgent and requires an immediate response, please include 'URGENT' in the subject line of the email, otherwise we will respond on our return

SAEs should be reported in the usual manner, as per the SAE Reporting Guidelines which can be found in section 13 of the ISF or via the website link: www.birmingham.ac.uk/research/bctu/trials/renal/starfish/starfish-link-base.aspx

Please ensure that the causality assessment is made and reported by a medically qualified doctor as soon as possible.

