



December 2023

Welcome to the second issue of the STARFISH Newsletter

Site Openings

We are over the moon to announce that we now have 37 sites open for the STARFISH trial.

1st to open - Kettering General Hospital

2nd - Lister Hospital

3rd - Royal Bolton Hospital

4th - University College London Hospital

5th - Royal Blackburn Hospital

6th - Glangwili Hospital

7th - Freeman Hospital

8th - Poole Hospital

9th - Liverpool University Hospital

10th - Stepping Hill Hospital

- 11th - Thomas Linacre Centre
- 12th - Royal Devon & Exeter Hospital
- 13th - Queens Medical Centre
- 14th - Gloucestershire Royal Infirmary
- 15th - St Michaels Hospital, Bristol
- 16th - Ninewells Hospital
- 17th - University Hospital, Monklands
- 18th - Royal Derby Hospital
- 19th - James Cook Hospital
- 20th - Guy's & St Thomas Hospital
- 21st - Charing Cross Hospital, London
- 22nd - Glasgow Royal Infirmary
- 23rd - Addenbrookes Hospital
- 24th - Leicester Royal Infirmary
- 25th - Musgrove Park Hospital
- 26th - Kings Mill Hospital
- 27th - Wythenshawe Hospital, Manchester
- 28th - Countess of Chester Hospital, Liverpool
- 29th - Great Western Hospital, Swindon
- 30th - Sandwell General Hospital, Birmingham
- 31st - Royal United Hospitals, Bath
- 32nd - Queen Elizabeth Hospital, Birmingham
- 33rd - Royal Hallamshire Hospital, Sheffield
- 34th - Wexham Park Hospital
- 35th - Morriston Hospital
- 36th - Whipp's Cross Hospital
- 37th - Queen Elizabeth University Hospital, Glasgow

We would like to say a massive 'Thank You!' to all the site team members for your support and hard work enabling these sites to open.

Recruitment

We have now recruited 12 patients to the STARFISH trial.

Royal Bolton Hospital - 3

Gloucestershire Royal - 3

Freeman Hospital - 1

Stepping Hill Hospital - 2

Thomas Linacre Centre - 1

Glangwili Hospital - 1

UCLH - 1



Recruitment Map & Sites List

Click here to view the recruitment map & list of sites on the Starfish webpage.

[VIEW](#)

Site Initiations/ Q&A Sessions

Site initiations are be in the format of pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigators and trials office team, hosted on Zoom.

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.

The PI and any Associate PIs must do this before the trial can open at their centre, though we recommend that anyone involved in research activities for the trial does so too.

Q&A Session Information

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

- 1st Monday of the month – 10:00 – 10:30
- 3rd Tuesday of the month – 10:30 – 11:00

Forthcoming dates:

Tuesday 16th Jan 2024 10:30 – 11:00am

Monday 5th Feb 2024 10:00 – 10:30am

Tuesday 20th Feb 2024 10:30 – 11:00am

Monday 4th Mar 2024 10:00 – 10:30am

Tuesday 19th Mar 2024 10:30 – 11:00am

Monday 1st Apr 2024 10:00 - 10:30am

Please register for a Site Q&A session [here](#)

What Do I Need Before The Trial Can Open At My Centre?

Current CVs (signed within the last 12 months): required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site.

<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/>

Good Clinical Practice (GCP) certificates: required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site. Please find GCP Certificate link below:

<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

Study specific training including the pre-recorded SIV presentation: Required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site. Please find the training system link below:

[STARFISH e-training link](#)

The training videos can also be accessed via the trial website:

<https://www.birmingham.ac.uk/starfish/training>

Attendance at a live virtual Q&A session: Required for the PI and Associate PI prior to opening, but we recommend anyone involved in trial delivery attends.

Registration information is available on the trial website, here:

<https://www.birmingham.ac.uk/research/bctu/trials/renal/starfish/trial-resources.aspx>.

Completed Delegation log (v2.0, 15-Dec-2022). A blank copy is available at the following link:

<https://www.birmingham.ac.uk/documents/college-mds/trials/bctu/starfish/starfish-site-delegation-log-v2.0-15-dec-2022.pdf>

Protocol signature page, signed by the PI (v3.0, 10-Oct-2022)

NIHR Associate PI Scheme

People who would not normally have the opportunity to take part in clinical research in their day to day role have the chance to experience what it means to work on and deliver a NIHR portfolio trial under the mentorship of an enthusiastic local PI.

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.

For more information visit: [nihr.ac.uk/AssociatePIScheme](https://www.nihr.ac.uk/AssociatePIScheme)



NIHR | National Institute for
Health and Care Research



When completing the delegation log, training and sending over your CV/ GCP Certificate, there are a few requirements:

CV

- Should be wet ink signed and dated within 12 months (or as per your trust policy)

GCP Certificate

- Should be dated within the last 2 years (or as per your trust policy)

Delegation Log & Training

When completing the delegation log there is corresponding training that must be completed depending on the tasks/ roles you have been delegated:

The following responsibilities should only be performed by a doctor/clinician:

- D - Confirm patient eligibility
- F - Prescribing of investigational product
- H - Assesses SAEs
- O - Training of clinicians to perform intratympanic injections
- P - Perform intratympanic injections

The following responsibility should only be performed by the PI:

- K - CRFs and DCFs review and sign off (PI only)

The following responsibility should only be performed by an Audiologist:

- Q - Perform AB words test
- R - Perform pure tone audiogram (blinded assessment)

Training must have been performed for any role related responsibilities, see below:

Responsibility key on Delegation Log Training required

C – Obtain informed consent Video part 1: Introduction and Consent (3 mins)

P – Perform intratympanic injections Video part 2: Local Anaesthetic Technique (2 mins)

P – Perform intratympanic injections Video part 3: Steroid Injection Technique (2 mins)

Q – Perform AB word test Video part 4: AB Word Testing (9 mins)

- Initially as long as all responsibilities have been covered by the site staff, further staff members can be added later (with the exception of AB word

testing)

- Audiologists are not required to appear on the log if performing their normal job role (standard of care), however AB word testing training is mandatory

Emails:

We appreciate that some emails are lengthy, however they do all contain important information. Please ensure all emails are read fully on receipt.

Screening Log:

Please ensure dummy data is entered on the TRAINING database and not the live database

Please ensure the Screening Log is fully completed in a timely manner

A reminder for staff to check all QOL booklet pages are complete before the patient leave, as we are getting some blank pages.

Christmas closure:

Birmingham Clinical trials Unit (BCTU) will be closed from 16:00, Wednesday 20th December 2023 until 08:00, Tuesday 2nd January 2024.

SAE reporting:

The STARFISH online database will be available over the Christmas period. SAEs should be reported in the usual manner as per the SAE Reporting Guidelines which can be found in section 13.1 of the ISF or via the website link: www.birmingham.ac.uk/research/bctu/trials/renal/starfish/starfish-database.aspx

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

From us all at BCTU, we would like to wish all of our STARFISH colleagues a very Merry Christmas and a Happy and Healthy 2024!



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