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From: Brendan Smith (Birmingham Clinical Trials Unit)
Sent: 09 August 2024 14:05
To: Starfish
Subject: STARFISH Newsletter August 2024

August 2024

Welcome to the fourth issue of the STARFISH Newsletter

Recent Updates

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

The STARFISH team are excited to start working with the QUINTET group <https://www.bristol.ac.uk/population-health-sciences/research/groups/social-sciences-health/quintet/>

QUINTET are a research group based in Bristol that has developed an effective intervention to optimise recruitment and patient participation in RCTs, called the QRI (QuinteT Recruitment Intervention). The QRI uses innovative qualitative research methods combined with quantitative recruitment data to understand an RCT's particular recruitment barriers, and then address these collaboratively with the RCT team. We hope this collaboration can further improve STARFISH recruitment and support the work sites are already doing to ensure this trial is a success.

Site Information & Recruitment

We have now recruited **99** patients to the STARFISH trial, with March the best month since opening the trial with **18** recruited.

We are over the moon to announce that we now have **51** sites open for the STARFISH trial.

Congratulations to **Addenbrooke's** for being the top recruiting site with **10**.

Congratulations to **UCLH** for being the top screening site with **66**.

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.

Addenbrooke's

Site Opened: 24-Oct-2023

PI: Matthew Smith aPIs: Nathan Creber, Thomas Hudson, Anna Kaleva

Screened: **25** Recruited: **10**

Charing Cross

Site Opened: 09-Oct-2023

PI: Matthew Rollin aPI: Mark Gabrawi, Benjamin Kennard

Screened: **2** Recruited: **0**

Countess of Chester

Site Opened: 30-Oct-2023

PI: Todd Kanzara aPI: Ahmed Yousef
Screened: **5** Recruited: **3**

Freeman Hospital

Site Opened: 21-Jul-2023
PI: Nicholas Dawe aPI: Phil Lindsey
Screened: **3** Recruited: **2**

Furness General

Site Opened: 20-May-2024
PI: Salama Zewail aPI: Sudip Ghosh
Screened: **3** Recruited: **0**

Glangwili Hospital

Site Opened: 30-Jun-2023
PI: Vinod Prabhu aPI: Kirsty Davies
Screened: **19** Recruited: **3**

Glasgow Royal Infirmary

Site Opened: 12-Oct-2023
PI: Ida Amir aPI: Lucy Li
Screened: **10** Recruited: **4**

Gloucestershire Royal

Site Opened: 30-Aug-2023
PI: Nina Mistry aPI: Kityee Chan
Screened: **15** Recruited: **7**

Great Western Hospital, Swindon

Site Opened: 09-Nov-2023
PI: Daniel Moualed aPI: Sofia Anastasiadou
Screened: **1** Recruited: **1**

Guy's & St Thomas

Site Opened: 02-Oct-2023
PI: Rosa Crunkhorn aPI: Presanna Premachandra
Screened: **35** Recruited: **5**

James Cook

Site Opened: 02-Oct-2023
PI: Anirvan Banerjee aPI: Harry Tustin
Screened: **2** Recruited: **0**

Kings Mill Hospital

Site Opened: 25-Oct-2023
PI: Paraskevi Tsirevelou aPI: Ahmed Shehata
Screened: **4** Recruited: **1**

Kettering

Site Opened: 21-Jun-2023
PI: Wendy Smith aPI: Jack Constable
Screened: **0** Recruited: **0**

Leicester Royal Infirmary

Site Opened: 25-Oct-2023
PI: Paramita Baruah aPI: Vasim Modak, Manuela Cresswell

Screened: **22** Recruited: **4**

Lister

Site Opened: 21-Jun-2023

PI: Ananth Vjendren aPI: Catherine de Cates

Screened: **8** Recruited: **0**

Liverpool University, Aintree

Site Opened: 02-Aug-2023

PI: Ahmed Youssef aPI: Mohamed Fiala

Screened: **6** Recruited: **0**

Luton & Dunstable

Site Opened: 01-May-2024

PI: Pranay Singh aPI: Laura Leach, William Wakeford

Screened: **2** Recruited: **0**

Manchester Royal Infirmary

Site Opened: 04-Jan-2024

PI: Simon Lloyd aPI: Amr Abdelhamid

Screened: **7** Recruited: **1**

Morrison, Wales

Site Opened: 04-Dec-2023

PI: Paramesh Puttasidaiah aPI: Richard Brown

Screened: **0** Recruited: **0**

Musgrove Park Hospital

Site Opened: 25-Oct-2023

PI: Alistair Mitchell-Innes aPI: TBC

Screened: **4** Recruited: **0**

Ninewells, Dundee

Site Opened: 27-Sep-2023

PI: Patrick Spielmann aPI: Vanushia Thirumal, Ahmed Elsayed

Screened: **16** Recruited: **5**

Poole

Site Opened: 25-Jul-2023

PI: Emma King aPI: Alex Dando

Screened: **17** Recruited: **2**

Princess Alexandra

Site Opened: 31-Jan-2024

PI: Elina Kiverniti aPI: Mohammed Bella

Screened: **5** Recruited: **0**

Princess Royal

Site Opened: 03-Jun-2024

PI: Andy Scott aPI: Karamveer Narang

Screened: **0** Recruited: **0**

Queen Elizabeth Hospital, Birmingham

Site Opened: 22-Nov-2023

PI: Peter Monksfield aPI: TBC

Screened: **4** Recruited: **0**

Queen Elizabeth University Hospital, Glasgow

Site Opened: 11-Dec-2023

PI: Georgios Kontorinis aPI: Sarah Ellis

Screened: **8** Recruited: **2**

Queen's Medical Centre, Nottingham

Site Opened: 18-Aug-2023

PI: Priya Achar aPI: Quentin Bonduelle

Screened: **15** Recruited: **3**

Royal Blackburn

Site Opened: 30-Jun-2023

PI: Surya Narayan aPIs: Devan Vora, Louay Salfity

Screened: **4** Recruited: **0**

Royal Bolton Hospital

Site Opened: 21-Jun-2023

PI: Vikas Malik aPI: Dillan Shetty

Screened: **9** Recruited: **7**

Royal Derby

Site Opened: 27-Sep-2023

PI: Owen Judd aPI: Simon Cole

Screened: **5** Recruited: **1**

Royal Devon and Exeter Hospital

Site Opened: 16-Aug-2023

PI: Rupert Ricks aPIs: Claire Perkins, Jack Dovell, Mariachiara Giali

Screened: **25** Recruited: **5**

Royal Hallamshire, Sheffield

Site Opened: 23-Nov-2023

PI: Jaydip Ray aPI: Matthew Farr

Screened: **0** Recruited: **0**

Royal Lancaster Infirmary

Site Opened: 20-May-2024

PI: Salama Zewail aPI: Sudip Ghosh

Screened: **0** Recruited: **0**

Royal London Hospital

Site Opened: 23-May-2024

PI: Kiran Jumani aPI: Meng Yip

Screened: **5** Recruited: **1**

Royal United, Bath

Site Opened: 21-Nov-2023

PI: Tom Mawby aPI: Oliver Wright

Screened: **0** Recruited: **0**

Salford Royal

Site Opened: 27-Mar-2024

PI: Simon Freeman aPI: Rejina Fameesh

Screened: **1** Recruited: **0**

Sandwell Hospital, Birmingham

Site Opened: 16-Nov-2023

PI: Yohanna Takwoingi aPI: Reham Ali, Claire Lingard

Screened: **12** Recruited: **7**

St John's Hospital

Site Opened: 01-Mar-2024

PI: Alex Bennett aPI: Louise McMurrin

Screened: **0** Recruited: **0**

St Michael's, Bristol

Site Opened: 21-Sep-2023

PI: Linnea Cheung aPI: Ross Mercer

Screened: **21** Recruited: **0**

Stepping Hill Hospital

Site Opened: 07-Aug-2023

PI: Milan Rudic aPI: Shameena Shinaz

Screened: **24** Recruited: **5**

Sunderland Royal Hospital

Site Opened: 08-Jul-2024

PI: Asil Tahir aPI: Peter Sudworth

Screened: **3** Recruited: **0**

Thomas Linacre Centre

Site Opened: 07-Aug-2023

PI: Aravind Bheemacharya Madhwacharya aPI: Mitanshi Luhana

Screened: **12** Recruited: **5**

UCLH

Site Opened: 21-Jun-2023

PI: Nischay Mehta aPI: Cillian Forde

Screened: **66** Recruited: **2**

University Hospital Coventry

Site Opened: 03-Jan-2023

PI: Emma Hoskison aPI: Andrew Lotfallah

Screened: **12** Recruited: **2**

University Hospital Lewisham

Site Opened: 21-May-2024

PI: Praneta Kulloo aPI: Constantin Dirla

Screened: **0** Recruited: **0**

University Hospital Monklands, Airdrie

Site Opened: 27-Sep-2023

PI: Arunachalam Iyer aPIs: Mahesh Jayalathge, Noah Evans Harding

Screened: **8** Recruited: **3**

Wexham Park, Slough

Site Opened: 30-Nov-2023

PI: Ram Moorthy aPI: Hasan Segana

Screened: **7** Recruited: **2**

Whipps Cross

Site Opened: 06-Dec-2023
PI: Kiran Jumani aPI: Noah Havers
Screened: **6** Recruited: **1**

Wrexham Maelor Hospital

Site Opened: 06-Feb-2024
PI: Huw Jones aPI: Lisa Williams
Screened: **4** Recruited: **3**

Wythenshawe, Manchester

Site Opened: 30-Oct-2023
PI: Sadie Khwaja aPI: Avantie Khudan, Haris Duvnjak
Screened: **46** Recruited: **1**

Ysbyty Gwynedd, Bangor

Site Opened: 23-May-2024
PI: Senthil Rajamanickan aPI: Faiza Ali
Screened: **3** Recruited: **1**

Recruitment Map & Sites List

Click [here](#) to view the recruitment map & list of sites on the STARFISH webpage.

Site Initiations/ Q&A Sessions

Site initiations are to 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 with 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:

Monday 2nd September 2024 10:00 – 10:30am

Tuesday 17th September 2024 10:30 – 11:00am

Monday 7th October 2024 10:00 – 10:30am

Tuesday 15th October 2024 10:30 – 11:00am

Monday 4th November 2024 10:00 – 10:30am

Tuesday 19th November 2024 10:30 – 11:00am

Monday 2nd December 2024 10:00 – 10:30am

Tuesday 17th December 2024 10:30 – 11:00am

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/researchplanning/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: [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/trialresources>

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

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

Protocol signature page, signed by the PI (v4.0, 18-Dec-2023)

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
- - 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

Site Support

We would like to introduce Andrew Williamson and James Arwyn-Jones.

Andrew is an ENT registrar from the West of Scotland deanery, and is the current chair of INTEGRATE, the ENT trainee research network. James is an ENT Registrar in the London North Thames deanery and is the Chair of the INTEGRATE Otology committee.

Their role in STARFISH will be to utilise INTEGRATE's collaborative trainee network to ensure as many sites as possible have the opportunity to recruit patients, and receive the support they need to make the trial a success.

If trainees have any issues within the study you can contact them at starfish.trial.advice@entintegrate.co.uk. STARFISH is also looking for regional leads to help manage the aPIs. If you may be interested then please contact the previous email address.

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.

STARFISH now has the highest number of registered aPIs in any ENT clinical trial at **71**.

For more information visit: www.nihr.ac.uk/AssociatePIScheme

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 for all eligible and ineligible patients.

Database Passwords:

Passwords for the STARFISH database will only last for 6 months. They will then need to be reset.

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

SAE reporting:

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/starfishdatabase.aspx

Any hospital admissions must be reported even if it may not appear to be related to the treatment.

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

Contacts:

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