Newsletter 1 |

78 Participants Recruited

50 Participants Randomised

6 Sites open to recruitment

14 Parent Interviews conducted

62 Parent questionnaires received

2 Staff Focus Groups conducted

Entering our fourth month of recruitment, sending a big thank you to all site teams for your efforts!
Welcome to new sites Bristol Royal Hospital for Children and University College London Hospital.
Wishing you all best with the FROG study

Recruitment

Site	Participants
Birmingham Children's Hospital	9
Bristol Royal Hospital for Children	Opened
Children's Hospital Oxford	10
Royal Belfast Hospital for Children	31
Leicester Royal Infirmary	26
University College London Hospital	Opened [2]

Congratulations to all!

Achieving 78 participants within 14-weeks is impressive Keep going!

Thank you for collecting parent/guardian questionnaires and patients/ parent/ guardians "consent to be contacted details" for taking part in interviews (WP2) and the consensus meeting (WP3).

We are close to completing interviews with final focus on:
*children or parents/guardians of children who have declined to take part (decliners)
*parents/guardians of older children
*parents/guardians of newly opened sites (Bristol &UCLH)

Clarification of Inclusion Criteria

The FROG trial is designed to randomise children to either invasive or non-invasive urine sampling methods.

Please remember the inclusion criteria are **not limited to children with a high clinical suspicion of urinary tract infection (UTI). Instead, any child for whom a urine sample is being requested to assess for possible UTI—regardless of the level of suspicion—should be considered eligible.**

This includes cases where urine testing is being performed to rule out UTI, even if the likelihood is low. The rationale for this broader inclusion is that **contamination rates, particularly with non-invasive sampling methods, are significant across all children**, not just those with confirmed or strongly suspected UTI.

Ensuring consistent application of the inclusion criteria is essential to the integrity and generalisability of the trial findings.

Data entry

Continue to enter clinical data on the eCRF screening and clinical databases on a weekly basis, and email "consent to contact lists" frogstudy@liverpool.ac.uk (WP2) and FROG@NICTU.hscni.net (WP3)
Important: Please document in the MACRO database any incidences whereby ***the child has passed urine***
****before approach***
****after approach***
****during the consent process***
Include the time the sample was obtained in MACRO.

DATES FOR YOUR DIARY

The next Investigator meeting will be held online.
This is a safe space for all with CI for Q&A, and sharing experience within the team.
Join us on Monday 29th September 10-11am

Health Service Use

Please email your photos of mock up trolleys and description of resources, staff and time for TUBC, CCU and SPA to FROG@NICTU.hscni.net

REMINDERS

Adverse events reminders

***Please remember to report any Adverse Events or Adverse Reactions** on the adverse event form in the eCRF/ MACRO database.

What is considered an adverse event (AE)? An unfavourable outcome that occurs during or after the use of the urine sampling method but is not necessarily caused by the sampling method should be reported. Complications of the study intervention/procedures (CCU, SPA and TUBC) **should also be reported** as AEs. An adverse reaction (AR) is defined as an AE that is deemed to be possibly, probably or definitely related to the sampling methods (CCU, SPA or TUBC).

How do we report serious adverse events (SAES)? SAEs/SARs are to be reported on the Serious Adverse Event Form in your ISF and sent to the NICTU by email (clinicaltrials@nictu.hscni.net) **within 24 hours** of the investigator becoming aware of the event.

What is considered a serious adverse event? Any untoward medical occurrence during the research that results in death, is life threatening, requires hospitalisation (admission), or prolongs existing hospitalisation, results in significant disability or incapacity, or is a congenital anomaly or birth defect.

Process reminders

Please provide parents/guardians with the pain (FLACC or FACES) and distress (SUDS) scales after administration of the sampling method whether they have consented to randomisation or not. Advise Parents/Guardians to complete these behavioural scales with their immediate response, not ponder over ratings, then collect the answer sheet or record their response with them.

Recruitment reminders

During Recruitment If one invasive urine sampling method is unavailable or inappropriate (i.e. SPA) then explain it is excluded upon approach or during the review of consent form. Discussing unavailable or inappropriate invasive methods can be confusing.

If a family consents to the observational component (WP1 But no randomisation to sampling method), please make it clear to them they are in the study. We know it's unusual to be able to decline randomisation but still take part in a study, so stress this and also explain the other aspects of the study; interviews and consensus meeting. Participant views are also important.

Tips for Recruitment, Process and Preparation

From Belfast and Leicester

Parents are responsive to the information video Ask parents to scan the QR code on their phone and open the video before leaving them to have a think about consent.

Make up participant packs in folders; parent info sheets, consent form, patient workbook (up to page 11) pain and distress scales, contact sheets, and our own checklist. This ensures we have everything to hand and don't need to keep going back and forth to ask parents questions.

Here at Leicester, we **ask clinicians to inform us even if they are performing a urine test simply to rule out a UTI** -it does not have to be based on classic UTI symptoms. That increases our range of recruitment. For example, even if a child comes in with febrile seizures and the team is busy ruling out all sorts of possibilities, we still manage to hop in with the FROG study, if they have UTI in the list! **We are toadally ready!!!**

A good line to use is: '*The doctor/nurse/clinician needs a urine sample to check for a urine infection; there are different ways we can collect the urine including CCU and TUBC +/- SPA. These are both(all) appropriate for your child. The advantages of CCU are that it doesn't involve a procedure; the disadvantage is that its slow and unreliable as it often shows infection when there isn't one. TUBC (+/- SPA) are quick and very accurate but can cause some distress, typically no worse than a blood test*'.

*We also inform parents that **there is a possibility the doctors may proceed with a TUBC if the child has not passed urine within the next couple of hours.** We reassure them that in our clinical areas, we use soft silicone catheters—not exactly the plastic ones mentioned in the PIS (Silicone is generally assumed to be much gentler and causes less discomfort and distress compared to plastic, though this can vary depending on what's available in the Trust.)*

Before approaching, double check that someone can perform the invasive method(s) on offer and that you have the equipment available. **We set aside dedicated catheterisation packs specifically for the FROG trial, so we do not have to use the standard ones stocked in the unit. Most of the clinicians and nurses are also trained on in and out catheter.*

Freddo FROGS are always well received!

