

CLEAR Newsletter



EDITION 2
SEPTEMBER 2018

Welcome to the second edition of the CLEAR Newsletter!



We'd like to take this opportunity to **thank you** for your continued support for the CLEAR Study.

We are delighted to say that **4 sites** are actively screening and **3 patients** have been recruited to-date.

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GET IN TOUCH

Please get in touch with any comments, suggestions or queries you may have.

Email the NICTU at:

CLEAR@nictu.hscni.net

Or give us a ring on:

02890 635 794

and ask to speak to a member of the CLEAR Team.



STUDY UPDATE

The 8-month pilot study commenced with the first patient-first visit which took place at Belfast City Hospital on 27th June, just 1 week after the CLEAR Trial received Sponsor Green Light Approval. Thank you to Dr Downey and his fantastic team!



Well done to Dr Kelly and the CLEAR team at Altnagelvin who have recruited 2 patients to-date!

The pilot study will include 10 sites from across the UK, and will finish at the end of January 2019. Importantly, progression to the main study is dependent on the results of the pilot.

Well done to Southampton and Princess Alexandra who have also opened to recruitment.

We hope to have the remaining 6 sites participating in the pilot study open in the coming weeks, so that together we can reach the funder target of 60 patients by the end of January.

1. Altnagelvin Area Hospital ★
2. Royal Free Hospital
3. Royal Infirmary of Edinburgh
4. Freeman Hospital
5. Royal Brompton Hospital
6. Belfast City Hospital ★
7. Ninewells Hospital
8. Princess Alexandra Hospital ★
10. Southampton General Hospital ★
11. Craigavon Area Hospital

FAQS

Q: Is a patient eligible for the study if they use HTS and/or Carbocisteine very occasionally/PRN?

A: Yes, the patient is eligible if this use is only PRN i.e. during an exacerbation, and the patient has not used HTS, Carbocisteine or any mucolytics within the 30 days prior to randomisation.

Q: Is a patient eligible for the study if they use 0.9% isotonic saline to reconstitute colomycin only?

A: Yes. Although the eligibility criteria excludes patients who take regular isotonic saline, this is allowed if used only as a mixer for colomycin powder.



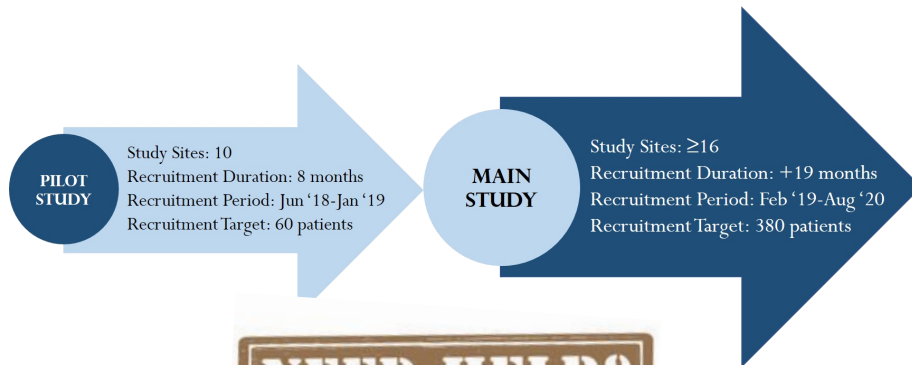
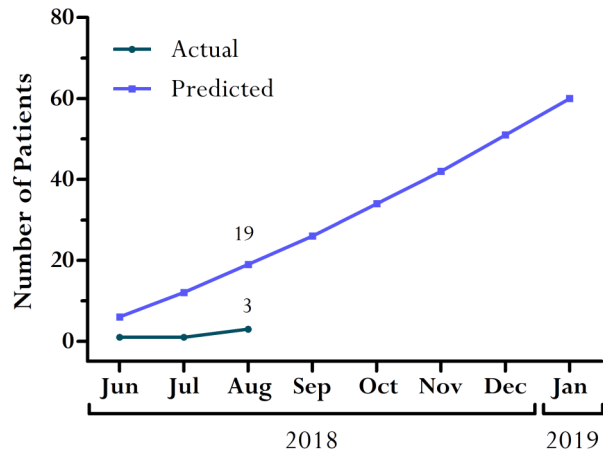
RECRUITMENT TARGETS

The overall recruitment period for the CLEAR study is 27 months, which began in June 2018 and will end in August 2020.



The recruitment target for the study is 380 patients, with 60 of these to be recruited during the 8-month pilot study. That's an average of 6 patients per site for the pilot!

Cumulative Recruitment: Pilot Study



Progression to the main study with the opening of additional sites is dependent on the results of the pilot.

We would really appreciate your continued efforts to get your site **open and recruiting** so that we can make better progress towards our targets!

NEED HELP?

- Contact us via the CLEAR mailbox or give us a call, we're happy to help!
- We will be in touch to offer you a fortnightly TC to assist with queries until your site is established.
- For any equipment issues, please contact PARI support at paritrack-support@pari.com and cc CLEAR@nictu.hscni.net. See the updated Trial Contact Details V5.0 in Section 1.0 of your Trial Manual for further information.
- Keep an eye out for our CLEAR FAQs document which we'll be distributing shortly along with some helpful PARI guidance.



Please enter all Screening Data onto MACRO by the 1st Monday of every month!

Remember to order additional devices from PARI to allow you to schedule your patient visits!

