

RAPID-I TRIAL NEWSLETTER



Issue 2, May 2020

Randomised treatment of Acute Pancreatitis
with Infliximab: Double-blind multi-centre trial

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RAPID-I Newsletter Issue 2 – May 2020

We are pleased to confirm that a huge amount of progress has been made since Issue 1 of the Newsletter was circulated in December 2019. **10 patients** have now been recruited into the trial, a further **4 research sites** have joined the Royal Liverpool University Hospital in patient recruitment and an additional site is able to follow-up patients that are transferred to them. We would like to welcome the teams at the John Radcliffe Hospital, Aberdeen Royal Infirmary, St Mary's Hospital, Hammersmith Hospital and Charing Cross Hospital to the trial. Thank you to all of the Investigators, Research Nurses and Research Administration Teams that worked to get the aforementioned sites open to recruitment and data collection, it is greatly appreciated by all of the central RAPID-I Trial Team.

For those Researchers based at sites which remain in set-up, we will continue to work closely with you, with the view to opening recruitment at your site as soon as possible. As soon as the restrictions on non-COVID-19 research ease, during what is likely to be a phased return to essential and high priority clinical research, we will be engaging with sites to set up, open and recruit as promptly as possible. We are confident that we will be able to carry our momentum forward once the COVID-19 situation has resolved.

Keep well and very best wishes from the RAPID-I Trial Team

COVID-19 UPDATE AND MESSAGE OF THANKS

As you are no doubt aware that due to the COVID-19 pandemic, **recruitment into RAPID-I has been halted at all research sites until further notice**, upon request by the Trial Sponsor. You should have received a letter confirming this postponement in March.

Although no further patients may be approached or recruited for the time-being, follow-up visits for patients already in the trial can and should continue, where possible.

For outpatients who are unable/not permitted to return to the hospital, we have made changes to the protocol (now version 8.0) to allow the following data/procedures to be completed remotely, either via telephone or by post:

- Patient questionnaires (EQ-5D-5L and Health Resource Use Questionnaire, HRUQ).
- Adverse event and concomitant medication data
- Day 28 urine pregnancy test for female patients of child-bearing potential

We will be releasing a telephone version of the EQ-5D-5L questionnaire shortly. In the meantime, please kindly post the questionnaire to the patient to complete and return.

The RAPID-I Trial Team would like to thank every single member of NHS staff for all of your efforts in supporting patients, and colleagues, in this very difficult time for everyone. **Thank you.**





PATIENT RECRUITMENT AND RESEARCH SITES UPDATE



Site Name	Patients Recruited
Royal Liverpool University Hospital	
Aberdeen Royal Infirmary	
John Radcliffe Hospital	
St Mary's Hospital	
Charing Cross Hospital	

THANK YOU!

Congratulations to the **Royal Liverpool University Hospital** team who have recruited 7 patients so far!

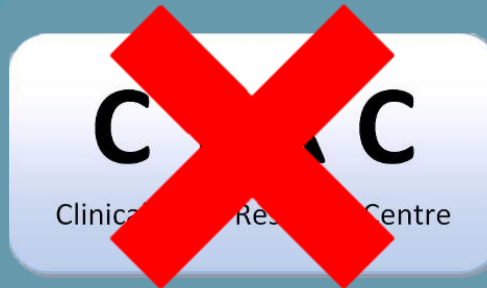
Special mention for the **Aberdeen Royal Infirmary** team who recruited their first RAPID-1 patient **two days** after opening to recruitment

Recruitment was postponed shortly after **St Mary's** and **Charing Cross Hospitals** opened RAPID-1, but their enthusiasm is unflinching and we look forward to restarting recruitment soon

We are the Liverpool Clinical Trials Centre

Previously known as the Clinical Trials Research Centre (CTRC), the CTRC merged with the Liverpool Cancer Trials Unit (LCTU) to form the joint Liverpool Clinical Trials Centre (LCTC).

The RAPID-I Trial Team are working to update the trial documentation as and when possible, so you may see references to CTRC and/or LCTC for the time being.



NIHR Associate Principal Investigator (PI) Scheme

The NIHR have developed the Associate PI Scheme to help develop junior doctors, nurses and allied health professionals to be PIs of the future. The scheme has been rolled out for surgical research studies with the aim that every NIHR portfolio trial, led or co-supported by the Surgery Speciality, will have an Associate PI at each site.

Scheme Structure

- Accessible to any junior doctor (FY1-ST8 or equivalent), nurse or allied health professional willing to make a significant contribution to the delivery of a surgical study at a local level
- Majority of studies will have a single Associate PI per site, at any given time
- The local PI remains responsible for the oversight of the study at site, including activities of the Associate PI



Applicants wishing to join the scheme should obtain approval from the local PI and the RAPID-I Trial Coordinator. They should register for the scheme by completing the [Associate PI Scheme Applicant Registration Form](#) and inform their local Clinical Research Network.

Throughout their involvement, Associate PIs will complete a Checklist, towards the end of the rotation or time period. The Associate PI applicant should meet with the local PI to review the Checklist and if completed satisfactorily, the PI will sign this off. The Checklist is then forwarded to the LCTC for final sign off.

The NIHR CRN will then issue a certificate confirming Associate PI status



RAPID-I National Trial Team Meeting Cancelled - May 2020

The RAPID-I National Trial Team Meeting scheduled to take place in Liverpool in May was **cancelled** due to the current COVID-19 pandemic. Thank you to all of those invitees who expressed their interest, we hope to arrange a replacement date in Liverpool as soon as we are able to do so.

In the meantime, please keep safe and we very much look forward to welcoming you all in Liverpool!