

RAPID-I TRIAL NEWSLETTER

Issue 1, December 2019

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

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HELLO AND WELCOME TO THE FIRST RAPID-I TRIAL NEWSLETTER!

We all hope that you had a wonderful Christmas holiday season in 2019!

Thank you to all of the research teams for their continued time and effort in setting-up RAPID-I at their site, with a view to open to recruitment as soon as possible in 2020. We appreciate the motivation and commitment for this hugely important trial up and down the country. Each research site receiving this newsletter may be in a slightly different phase, either continuing to recruit patients, nearing the final stages of site set-up, or perhaps beginning site set-up. Please do not hesitate to pick up the phone and contact the trial team should you have any queries. The first trial patient is always the most challenging, but subsequent patients are much, much easier. We are delighted to be recruiting patients are looking forward to opening a number of research sites at the start of 2020!

Best wishes from the RAPID-I Trial Team



RECRUITMENT AND SITES

RAPID-I opened to recruitment on 24th April at the **Royal Liverpool University Hospital**. We have since completed **site training visits** at a number of hospitals nationally:

Northern
General
Hospital
(Sheffield)

University
Hospital
Aintree
(Liverpool)

Imperial
College
Healthcare
NHS Trust

John
Radcliffe
Hospital
(Oxford)

Aberdeen
Royal
Infirmary

St James'
University
Hospital
(Leeds)

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

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We are still looking for new **secondary**, or **tertiary** care hospitals to take part in the trial - if you know of any interested sites or Investigators, please get in touch with the RAPID-I team!

SITE INCLUSION CRITERIA – PATIENT RECRUITING

- Secondary or tertiary care NHS Hospital providing adult A&E, Gastroenterology and General Surgical services
- Gastroenterology services with expertise in biologic therapies
- Principal Investigator (emergency medicine physician, gastroenterologist or surgeon/physician responsible for management of acute pancreatitis patients)
- Pharmacy Department or separate biologics preparation area with capacity and capability to prepare the trial infusion with **36 hours of onset of the patient's abdominal pain**

Site Greenlight Checklist

- Copy of delegation log to include the minimum required personnel (PI, Lead Research Nurse and Unblinded Research Nurse, Trial Pharmacist/Technician)
- CVs and GCPs for all delegated staff included on the log, signed and dated within the last three years
- Completed site suitability assessment questionnaire
- Confirmation of Capacity & Capability in England, or R&D approval in Scotland
- Agreed & executed Research Site Agreement



All secondary care centres must have the capacity and capability to transfer patients to a participating tertiary care centre with whom the secondary care centre is networked

Investigator's Meeting Liverpool April 2020

In April 2020 we plan to hold a Principal Investigators meeting in Liverpool. The purpose of the meeting will be for Investigators and Research Nurses to share their valuable experience of running RAPID-I at their respective sites with other Investigators and research teams at all stages (recruiting and in set-up).

Invites will be sent to research teams in the new year!



Liverpool Clinical Trials Christmas Closure

The LCTC office is closed from 5pm on the **20th December 2019** and re-opens 2nd January 2020.

There will be office cover available on 27th December for the management of safety reporting and dealing with other urgent enquiries.

If you have an enquiry requiring a response on 27th December please either call **0151 795 8759** or alternatively email grace.thomas@liverpool.ac.uk and abib@liverpool.ac.uk

The IS helpdesk is available on working days throughout the closure period (Mon – Fri excluding bank holidays). Telephone **0845 68 00 951**.

If you experience issues with the randomisation system during the Christmas period, please use one of the **back-up randomisation envelopes** provided!

THANK YOU!

The RAPID-I Trial Team would like to express our thanks to all of the research teams across the UK that continue to work on the trial, not only in contributing to patient recruitment but also those teams that are working to set-up RAPID-I at their site. Have an enjoyable Christmas break!

