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Sent: 17 October 2019 12:22
Subject: ADAPT-Sepsis Newsletter - October

ADAPT-Sepsis October Newsletter

Biomarker-guided antibiotic duration for sepsis

@AdaptSepsis Trial Website Trial Email

Welcome to the ADAPT-Sepsis newsletter! Please let us know if you have any suggestions for improvements or information you would like to see included on a monthly basis. New this month - Question Corner!

Please click on the headers below which will take you to the different sections.

Trial Update

Hello all, welcome to the October issue of the ADAPT-Sepsis newsletter! We have now recruited 672 to date, and still counting!

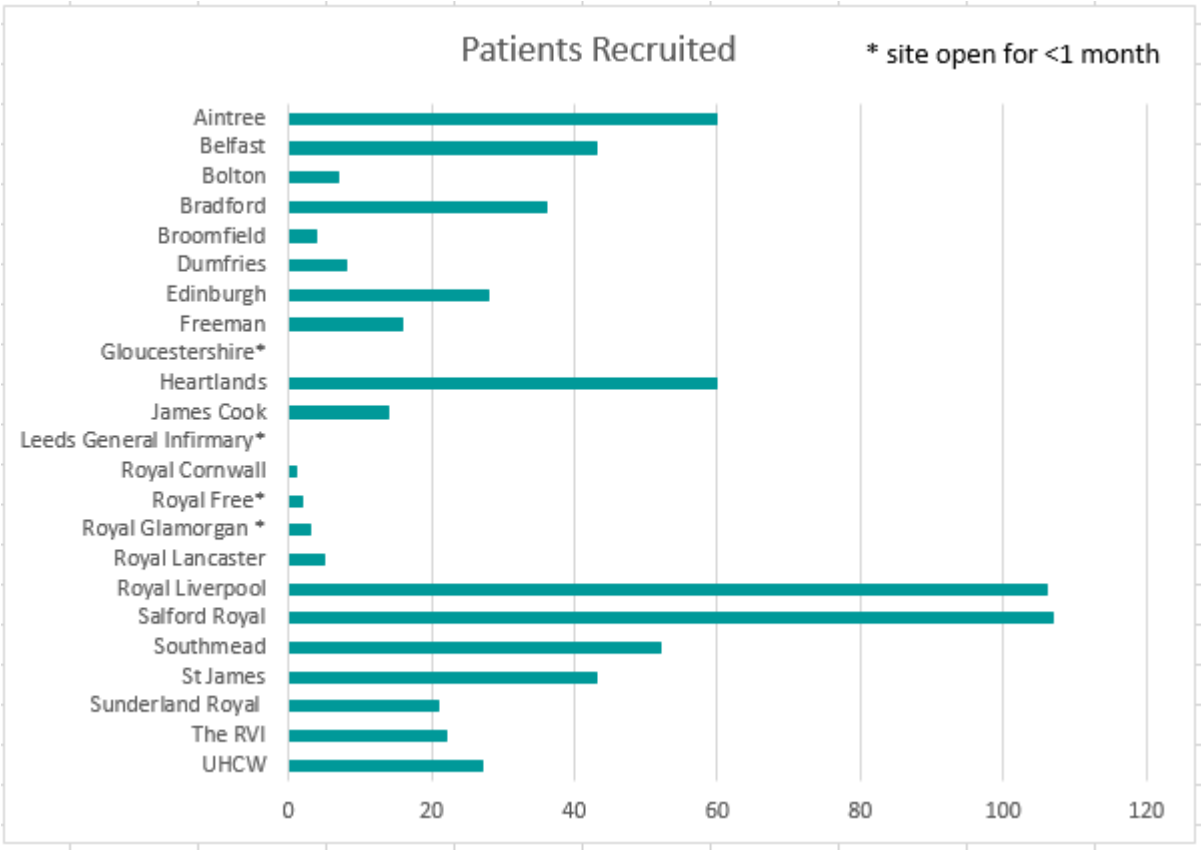
Since our last update we have welcomed Royal Free, Leeds General Infirmary, Gloucestershire Royal and Wythenshawe, a thanks to the teams at those sites for your hard work getting ready for the green light!

Trial Milestones

672 patients recruited so far

24 sites open to recruitment

4 further sites initiated to date



Training Materials

We have developed some training slides for non-GCP trained staff both on and off ICU, who are delegated to receive/disseminate the antibiotic protocol stoppage advice. The slides highlight both the trial intervention, and key GCP principles relevant to their role. The PowerPoint is available on request - please let us know if you would like a copy.

We also have an ADAPT-Sepsis trial poster suitable for staff areas, which aimed towards screening and identification of patients suitable for enrolment. Again, please get in touch with the trial team if you would like a copy.

Sepsis Evidence Update

ADAPT-Sepsis is important and timely for the NHS, as the early and potentially prolonged use of broad-spectrum antibiotics is increasing. The recommended duration of antibiotic therapy for sepsis is based on evidence of low quality that may lead to an overuse of antibiotics, contributing to the development of antimicrobial resistance, which is both a national and global priority. An internal re-review has been undertaken by NICE of their Diagnostic Guidance 18, and no new evidence sources have been identified to add to the already low quality evidence based that has resulted in the commissioning of the ADAPT-Sepsis trial. Therefore, ADAPT-Sepsis remains crucial nationally and internationally to help progress a definitive answer to the use of PCT and CRP biomarkers in helping to determine the duration of antibiotic treatment for sepsis.

Learning Points

Training for junior doctors

Following the rotation of junior doctors a couple of months ago, using trainees on the trial can be a great way to get more staff involved in raising trial awareness on ICU, and also to deliver the intervention, particularly during times where the research team may not be around (ie weekend for Mon-Fri teams). Sites have contributed to junior doctor training by doing a short talk on critical care research at inductions, creating memos to give out at the morning handover, or providing a bed area resource file with useful information in (research team contact details, trial summary, eligibility criteria and what to do on discharge). This has been a real asset to the trial, so if you would like to explore this option at your site, please let us know if there's any additional trial materials we can produce to assist with this.

Recruiting patients with a DNAR

We appreciate that sometimes it can be difficult to assess whether it's appropriate to screen a patient for a trial if they have a DNAR in place. As a rough guide, we ask you to review the reason why a DNAR might be in place; if this is relating to the patient choosing their treatment options, it may not be appropriate to consider them for the trial, and we ask you to use your clinical judgement. However, if a DNAR is in place due to a clinical decision relating to the possibility of the patient surviving resuscitation, then please do proceed to screen the patient for the ADAPT-Sepsis trial.

Obtaining retrospective consent

For patients who are recruited onto the ADAPT-Sepsis study using Personal Consultee or Trust Nominated Consultee assent, retrospective consent should be obtained once the patient regains capacity. It's good practice to make 'best efforts' to obtain consent retrospectively. We ask you to use your clinical judgement on how many times you should attempt to contact the patient, but as a general rule we would advise a phone call, followed by sending out the trial information and PIS/consent form. If the Day 28 Follow Up time point has passed, and you have not heard back from the patient, as per Section 2.7.1 consent to collect data for follow up time points will be assumed. Please ensure that any attempt to gain retrospective consent is clearly documented in the patient notes/electronic record.

Communication with patients

We are aware that some sites provide a cover letter to put with the trial information/consent materials that may be sent home with the patient. If this is standard practise at your site, please ensure that the trial logo is not included on the letter, as these materials haven't been produced by us, and therefore we have not obtained ethics approval to provide them to patients.

Question Corner

Do consultants receiving the stoppage advice have to have GCP training?

The protocol antibiotic stoppage advice must be sent initially to only members of staff who are listed on the delegation log. The email can then be forwarded on to other members of staff not related to the trial. However, consultants who are listed on the delegation log to receive the trial advice do not have to have GCP training.

In relation to the Initial Care Bundle, when does 'time of presentation' start?

Time of presentation starts either at the time of triage in the emergency care department, or if the patient is already in hospital, from the earliest chart annotation consistent with all elements of sepsis or septic shock, ascertained through chart review.

News

Currently sites in England, Wales and Northern Ireland can obtain telephone consent. We will soon be submitting a substantial amendment to allow Scottish sites to obtain telephone consent as well. Keep an eye on this space for news about the amendment!

Co-enrolment

Below is our current list of approved co-enrolling trials with more in progress (newly signed off trials in green);

A2B, A-STOP, BIT (Immune biomarkers and clinical outcome in trauma patients), BLING III, FLO-ELA, GenOMICC, ILoNIS, ILTIS, INTACT, PHIND, PQIP, Proteomic and genomic analysis of hepatopancreaticobiliary cancers, RADAR-2, REALIST, RESORP, REST, SNAP-IT, STARRT-AKI, STRESS-L, The 65 Trial, SQUEEZE, Understanding stroke-induced B cell changes and their relationships with stroke-associated infection and VACIRiSS.

Co-enrolment with observational studies is a fast tracked process. Where co-enrolment with observational studies will take place, please forward the relevant trial protocols for our records and approval.

For interventional studies, we will conduct a thorough review process with the respective coordinating teams. Please inform us of any current or upcoming interventional studies to prioritise.