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From: adaptsepsistrial, Resource
Sent: 04 February 2020 16:24
Cc: adaptsepsistrial, Resource
Subject: ADAPT-Sepsis February Newsletter

ADAPT-Sepsis February 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.

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

Trial Update

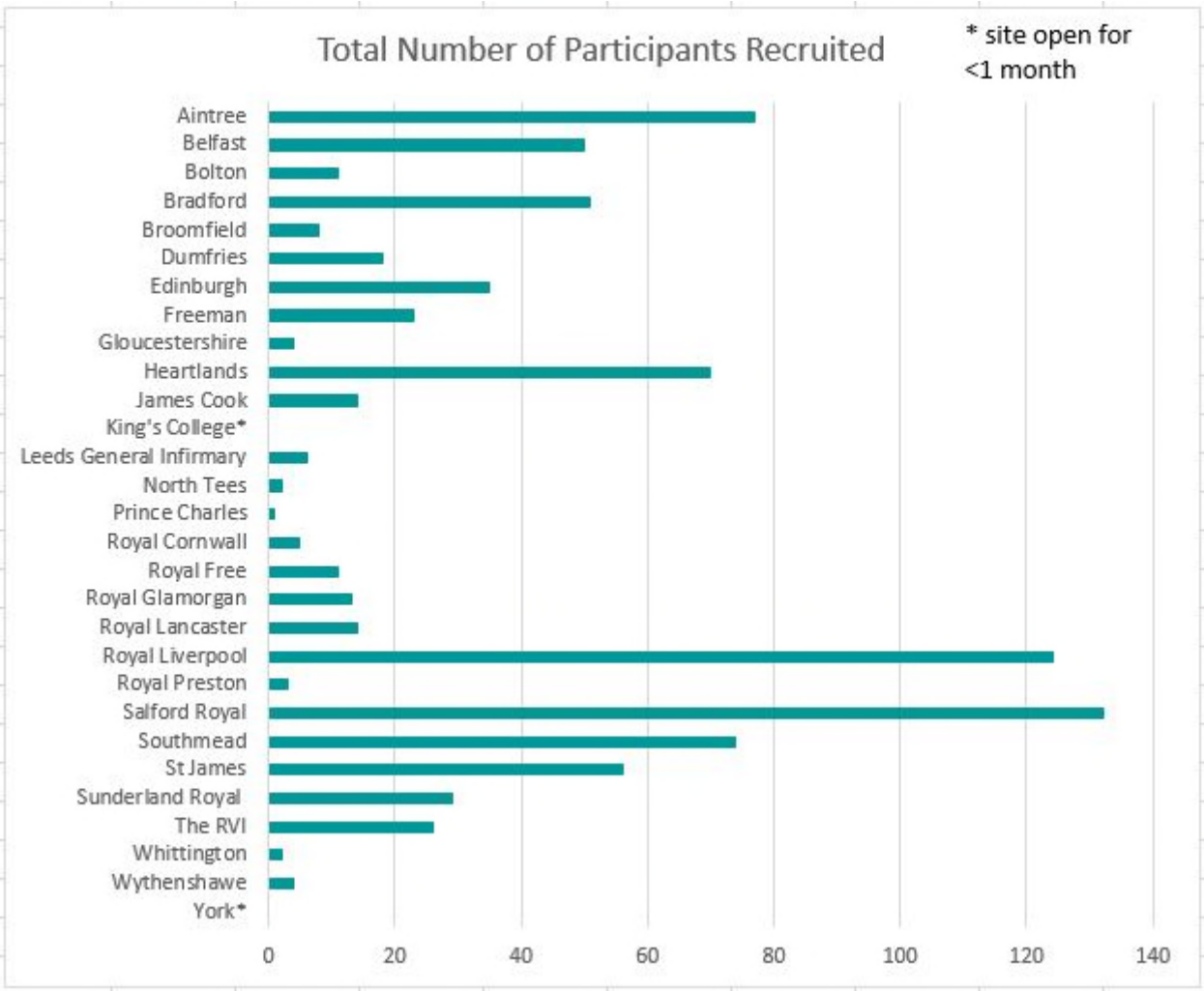
Hello all, welcome to the February issue of the ADAPT-Sepsis newsletter! We have now recruited 895 participants to date, and so are racing towards our 900th! A big thank you to all of our research teams for their hard work in allowing us to get to this stage.

Trial Milestones

895 patients recruited so far

29 sites open to recruitment

2 further sites initiated to date



KUDOS!

Welcome to Kudos, an award we'll be giving out each month to celebrate and highlight any above-and-beyond efforts on the ADAPT-Sepsis trial. Kudos this month is awarded to:

the teams at North Tees and Royal Preston, for their hard work, engagement and fantastic starts on the trial; **thank you** to you both!

Please let us know if you would like to nominate anyone for their hard work.

Eligibility Case Study

- Patient identified to have possible Hospital-acquired Pneumonia (HAP), and suggested to start antibiotics at 11am. Organ support started and patient transferred to ITU
- Antibiotics were actually started at 6pm
- Sepsis identified and confirmed in the notes 7.40am the following day
- Patient randomised to the ADAPT-Sepsis trial
- The 24 hour clock was started when the patient was given antibiotics at 6pm - not when sepsis was confirmed the following morning, as these antibiotics were given due to the patient's deterioration and increasing organ dysfunction in response to HAP.

Learning points:

a) a good understanding of the timeline of the patient's treatment, and reasons behind treatment decisions

b) Good contact with the trial team at Warwick CTU to discuss the case, including ongoing contact as the situation developed

Consent Workshop

We will be holding a consent workshop for all ADAPT-Sepsis sites, in joint with sites taking part in STRESS-L
This will be to identify and address particular challenges of consenting patients to critical care trials, and ways around these.

Tuesday 3rd March 2020 – 14:00-15:30
or
Monday 9th March 2020 – 11:00-13:30

Please keep an eye out for the agenda and dial-in details, which will be circulated shortly!

Learning Points

Stopping and restarting antibiotics

When antibiotics are changed from IV to ORAL; if these are still treating the initial infection causing organ dysfunction, please continue the intervention, and continue to take the daily blood samples.
Once all antibiotics have stopped, press stop on the daily data tracker, and halt the daily blood samples. Should antibiotics be restarted, these will be entered as follow up antibiotics. Please do not restart the daily blood sampling.

Blood samples which cannot be processed

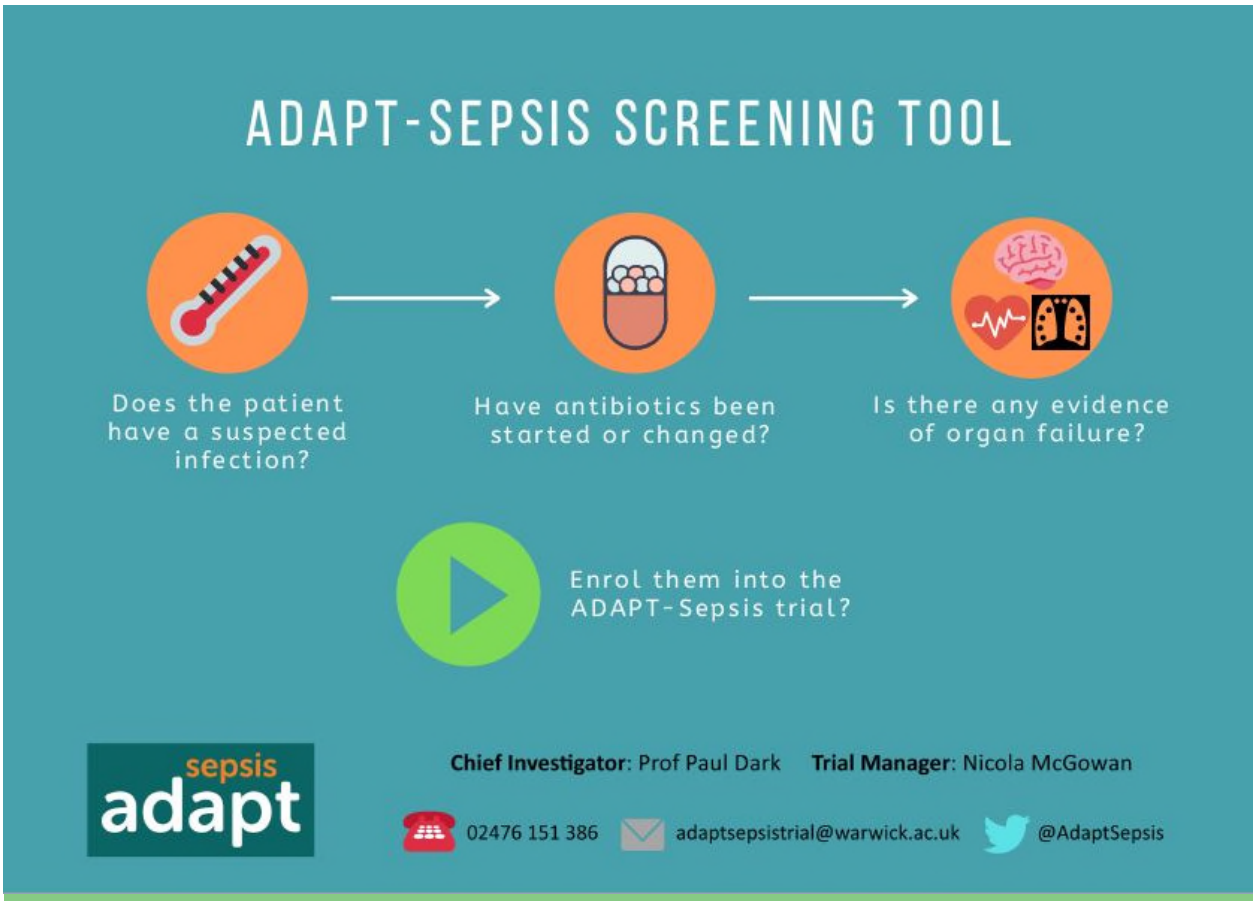
For those of you working on the lab side of the trial, there is currently no option to confirm that a blood sample has spoilt/haemolysed/cannot be processed for a technical issue. If

this occurs, please discard the sample, and inform either the Warwick trial team or your local research team that the clinical team should follow standard care advice for that day. Please remember not to provide any details as to why no advice will be sent, as the research team are blinded. Please let us know of any incidences of blinding, so that these can be logged for our records.

Language Barriers and Patients without NHS Numbers

When patients and/or their family members do not speak English, we ask sites to use their discretion to decide whether it would be appropriate to recruit them into the trial. If you have local translation services available, and are confident these would be able to be utilised going forwards, particularly when the patient regains capacity, and to obtain ongoing consent, then you are free to proceed to randomisation. If you do not have confidence in these services being available, please do not recruit the patient.

If a patient doesn't have an NHS Number, we have now established that you are able to proceed with randomisation. This decision has been made in accordance with advice from our Trial Management Group.



Look out for our screening tool, which will be arriving in the post at your Trust soon! Please get in touch if you have any questions.

News

Over the next few months we will be arranging teleconferences with sites in order to discuss screening, recruitment and provide an opportunity to raise any concerns or questions. We would be grateful if you could look out for our emails about this in order to schedule these as effectively as possible. We hope these will be good opportunities to discuss the trial, and check whether there's anything we can do to support you in your recruitment.

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, **REMAP-CAP**, RESORP, REST, SNAP-IT, STARRT-AKI, STRESS-L, The 65 Trial, SQUEEZE, TBI Cortisol, **TREATT**, 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.