ADAPT-Sepsis—June 2018 Newsletter

BiomArker-guided Duration of Antibiotic treatment in hospitalised PaTients with suspected Sepsis

Biomarker-guided antibiotic duration for sepsis

Trial Update

Our first two trial sites, James Cook and Salford Royal, have been performing brilliantly and have helped the trial achieve its best month yet: **10** patients have been recruited in May.

We are also delighted that Bradford Royal Infirmary are open and have recruited their first participant!

We look forward to meeting the teams at East Kent, St James, Royal Liverpool and Sunderland Royal over the coming weeks.

We will be attending the Critical Care Research Forum this week. Feel free to visit our working group session at 12:45 on Friday June 8th.

Milestones so far

- 6 sites initiated to date
- Trial opened January 2018
- First patient recruited January 2018
- ***18 patients recruited so far!***

Frequently Asked Questions

- Is there any funding available for us as a site to be involved in the trial?

There is a per patient payment of £50. NHS Treatment costs have been included for analysis of CRP and PCT within trial. PCT wastage costs will also be covered for the duration of the pilot phase.

- When should the 1st blood sample be taken?

The first research blood sample (baseline) must be taken within 24 hours of the patient receiving their first antibiotics for suspected sepsis. The lab must then analyse the sample and advice be returned **within 24 hours** of the blood sample being taken. Advice for all subsequent daily blood samples will be returned in the **same calendar day** that the sample was taken.

In the event that the patient is randomised later in the day and the lab are unable to analyse and enter the results within the same calendar day, the sample can be stored in the lab overnight for processing the following day, however, the advice from the baseline sample **must be received prior** to receiving the Day 2 treatment advice.

- Are point of care devices compatible with the trial?

The trial will not be supporting POC devices as the performance of these devices differs greatly from laboratory analysers.

- Should time of antibiotic prescription or administration be recorded?

Eligibility — the 24 hour clock should start when a patient receives their first antibiotics for suspected sepsis, not the time the antibiotic was prescribed.

Data entry — enter the start and stop times of antibiotic administration, not time of prescription or dispensing. If an exact time is not known, an estimate should be provided.

Eligibility Clarifications

The 24 hour clock for antibiotic treatment starts when a patient is administered antibiotics specifically for a suspicion of sepsis, regardless of if they have had previous antibiotic treatment for a different infection. We have included a couple of examples to help illustrate this:

Scenario 1:

64y male patient arrives at A&E with signs and symptoms of a lower respiratory tract infection (pneumonia) of low severity, with no clear signs of sepsis. It is not thought safe to discharge the patient home due to complex social circumstances and the fact he has not been drinking very well and has a persistent fever. He is treated in the Emergency Assessment Unit (EAU) overnight with a single first line iv community acquired antibiotic based on local hospital guidance and iv fluids. The following day, 36 hours after admission, his condition is worsening with a low blood pressure - not improving with iv fluids - his oxygen saturation is falling despite mask supplementary oxygen, his urine output is falling and he has become confused. He is reviewed urgently by the EAU team, his iv antibiotics are escalated to dual therapy appropriate for severe community acquired pneumonia and sepsis, and he is referred to critical care. Overall, he has received 36 hours of iv antibiotics since admission but has only just received iv antibiotics for a severe infection/sepsis – he is therefore eligible for consideration for recruitment into the ADAPT-Sepsis study assuming the senior treating clinician agrees.

Scenario 2:

A 64y female patient is day 3 after large bowel resection surgery for a tumour. She is making good progress and starting to take oral fluids. An old iv cannula site is looking red, feels hot to touch and she has a mild fever. Her treating surgical team decide that she may have a cellulitis and treat her with iv flucloxacillin through another iv canula having already removed the old canula. The following day, 36 hours after commencing iv flucloxacillin, she becomes very unwell with clear signs of septic shock. Her iv antibiotics are escalated to broad spectrum – including two agents – and she is referred to critical care. Although she has received at least 36 hours of iv antibiotics, the iv antibiotics for septic shock have only just been commenced and she is eligible for consideration for recruitment to ADAPT-Sepsis assuming the senior treating clinician agrees.

The ADAPT-Sepsis team

- Prof Paul Dark—Chief Investigator
- Scott Regan—Senior Project Manage.
- Nicola McGowan—Trial Manager
- Johnny Guck—Trial Coordinator
- Dipesh Mistry—Statistician

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Visit our trial website….

- https://warwick.ac.uk/fac/med/research/ctu/trials/adaptsepsis/

Screening logs

- Please remember to send in your screening logs for this month by 25th June.
- Either complete our electronic spreadsheet or scan and email a paper copy (v2.0, 19/03/2018).