



Biomarker-guided antibiotic duration for sepsis

ADAPT-Sepsis—May 2018 Newsletter

Biomarker-guided Duration of Antibiotic treatment in hospitalised Patients with suspected Sepsis

Site Set Up

We have received a huge level of interest from sites across the UK and we would like to thank everyone for their support.

Over 90 sites have expressed interest in the study so far and we are in the process of selecting and opening our initial 12 pilot sites.

We would like to welcome aboard James Cook and Salford Royal as our first trial sites! Congratulations to both on recruiting your first trial participants. We would also like to extend a huge thank you to the team at James Cook University Hospital for all of their hard work and for helping to iron out our teething problems!

Further site initiations are planned for the coming weeks.

Milestones so far

- ◆ Full REC approval granted Oct 2017
- ◆ 6 sites initiated to date
- ◆ Trial opened January 2018
- ◆ **First patient recruited January 2018!**
- ◆ 9 patients recruited so far



The ADAPT-Sepsis team

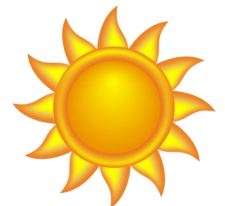
- ◆ Prof Paul Dark—Chief Investigator
- ◆ Scott Regan—Senior Project Manager
- ◆ Nicola McGowan—Trial Manager
- ◆ Johnny Guck—Trial Coordinator
- ◆ Dipesh Mistry—Statistician

Nessa Nevels has now left her post in the trial. Please direct all correspondence to adaptsepsistrial@warwick.ac.uk or call **02476 151 386 (Nicola McGowan)**

Visit our trial website...

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

We hope you enjoy the bank holiday!



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. We have calculated CRN support costs of 2 hours nursing time per patient for recruitment and consent. NHS Support and Treatment costs have been included for laboratory analysis of CRP and PCT within trial.

- ◆ How long will the trial be open for and what is the recruitment target?

The pilot phase will end in July 2018 whilst the main phase is planned to complete at the end of March 2020 with the aim of recruiting 2760 patients.

- ◆ What would be the per site recruitment target?

Approximately 4 patients per month or 1 per week.

- ◆ How will we access the daily treatment advice?

Daily treatment advice is automatically generated each day a participant is receiving the intervention. This advice is available on the trial database and can be automatically emailed to the necessary clinical and research staff.

- ◆ Is weekend cover required?

Whilst recruitment can cease over the weekend, daily research blood sampling must continue 7 days a week. We have a number of solutions to navigate this requirement so let us know if you would like some advice.

Lessons Learned

- ◆ Eligibility

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. For example, a patient is admitted to hospital with community acquired pneumonia and are given broad spectrum antibiotics and the patient does not require critical care. After a couple of days the patient's condition deteriorates and they are now suspected to have sepsis and as a result the patient's antibiotics are changed due to the suspicion of sepsis. This is the time point at which the trial's 24 hour clock starts.

- ◆ Documentation of consent procedure and eligibility

The QA team at Warwick Clinical Trials Unit have advised that recent monitoring visits across a number of trials have identified an overall lack of documentation particularly for the consent procedure and review of the eligibility assessment—these are areas which will be focused on during ADAPT-Sepsis monitoring visits and so please ensure that these are documented in full in the participants medical notes.

Screening logs

- ◆ Please remember to send in your screening logs for this month by 28th May.
- ◆ Either complete our electronic spreadsheet or scan and email a paper copy (v2.0, 19/03/2018).