ADAPT-Sepsis—December 2018 End of Year Newsletter

Trial Update

Hello all, the ADAPT–Sepsis trial has had a very busy and successful year. We opened to recruitment in January and have been able to see how the trial fits into the NHS setting. Our initial 9 centres have all contributed to help us to meet our pilot progression criteria and progress to the main phase of the study. We are really grateful for your input!

Now that we have advanced to the main trial we are aiming to expand across the UK to around 48 sites. Since the pilot phase has ended we have welcomed St James' University Hospital to the trial who have recruited their first participant. Congratulations!

We hope to open UHCW ahead of the Christmas break and looking forward to attending further site initiations in the new year as we bring further sites into the fold. The experience we have gained from our pilot sites will prove invaluable during this time.

Milestones

- Open to recruitment January 2018
- Pilot phase completed end of September
- 13 sites initiated to date
- 10 sites open to recruitment
- *169 patients recruited so far!*

State of the Art Conference

Nicola McGowan and our CI, Prof Dark, will be attending this year's state of the art conference from the 10th to the 12th of December.

We will be staffing a research stand and hosting an informal investigators meeting at 16:00 on the 11th in the Albert room. Please feel free to drop by for a chat or more information about the trial!

Christmas cover

As the Christmas period is fast approaching, please let us know if you would like any assistance in planning ahead for this period. Whilst the ADAPT-Sepsis trial team will be out of the office from the 21st December to 2nd January, we will be monitoring the email accounts for any emergencies so please don't hesitate to get in touch.

Screening logs

- Please remember to send in your screening logs by 10th December. We will now request these every 2 weeks.

Get in touch Please direct all correspondence to **adaptsepsistrial@warwick.ac.uk** or call **02476 151 386 (Nicola McGowan)**

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Site Set Up FAQs:

How many sites will participate in ADAPT-Sepsis?
We are aiming for 48 sites across the UK.

What are the timelines for being open for recruitment?
We are now working with sites for the main phase of the trial and will be opening sites until the end of September 2019.

Is there any funding available for us as a site to be involved in the trial?
Yes – There is a per patient payment of £50.
We have calculated NHS support costs of 2 hours nursing time per patient for recruitment and consent.
NHS Treatment costs have been included for laboratory analysis of any additional CRP and PCT tests within trial.
PCT set-up and assay wastage funding where applicable is available for sites not currently providing PCT Contact adaptsepsistrial@warwick.ac.uk for further details for your site

Can I still be involved in the trial if our site does not provide local laboratory PCT analysis?
Yes – we can work with you and your team to facilitate NHS adoption of a laboratory PCT assay for your Clinical Biochemistry Department, this includes financial support.

Interested in taking part?

Please get in touch to learn more about the trial and to complete a feasibility questionnaire!

Is the trial funded by a commercial partner?
No – the trial is funded via the NIHR and with NHS support. Thermo Fisher Diagnostics Limited, by way of a Memorandum Of Understanding, have agreed to assist the trial team with the adoption of new laboratory PCT assays into the NHS as required. Thermo Fisher have no involvement in the design and delivery of the trial, the trial data or its findings, and trial dissemination.

We already use daily CRP though do not have a protocol for discontinuation of antibiotics. Should we be selected as a site would "standard care" be our current practice, with the "standard care + CRP" being use of a CRP based protocol, or would be have to stop measuring CRP routinely for patients in the "standard care" group?

We do not insist that you continue this practice but, equally, can continue to measure CRP daily if this an agreed unit level standard at your hospital. We use an extra trial blood sample in order to test either CRP or PCT levels, and you would be blinded to the result.

We already use PCT though do not have a protocol for discontinuation of antibiotics. Should we be selected as a site would "standard care" be our current practice, or would be have to stop measuring PCT routinely for patients in the "standard care" group?

You will not be able to continue routinely measuring PCT for trial patients and must be able to ensure a position of equipoise for an individual trial patient. This is because the guidance for stopping antibiotics utilising PCT is better defined than the guidance for CRP. We do not insist that you abandon using PCT for patients not enrolled in this study.

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

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