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From: STRESS-L, resource
Sent: 21 March 2019 12:01
To: STRESS-L, resource
Subject: STRESS-L March Newsletter, Issue 7

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@StressLTrial Trial Website

Welcome to the new email format of the STRESS-L Newsletter which we hope is more accessible! 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

Recruitment & Milestones

Investigator Meeting & Feedback

Breakout Sessions Feedback

Data Management Update

Co-enrolment update

UKCCRG

Trial Update

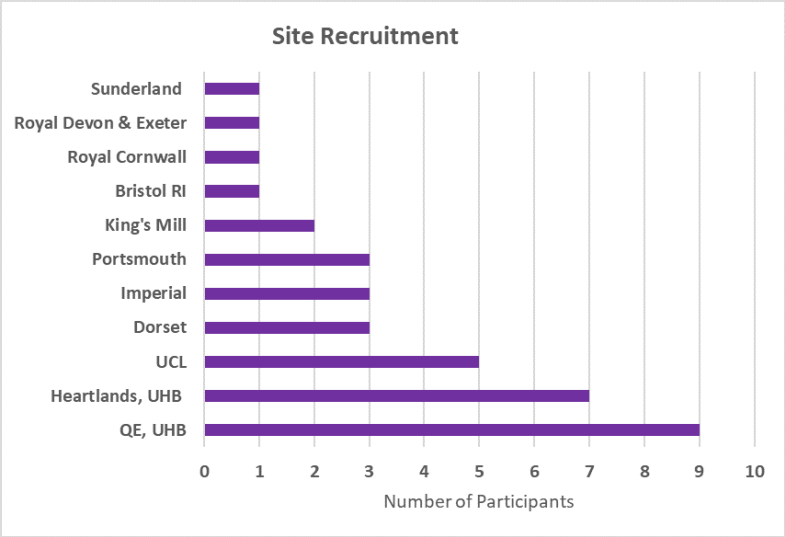
The STRESS-L trial team would like to celebrate our highest recruiting month ever in February — 7 **patients** enrolled in the shortest month of the year!

A special thanks goes to the Royal Devon & Exeter for recruiting their first patient, Queen Alexandra for recruiting their first three in such as short amount of time and King's Mill for all their hard work with recruiting their second patient.

We are also very pleased to say Heartlands set a new record with three patients recruited within 1 week - thank you!

We enjoyed visiting Addenbrookes earlier this month for the SIV and look forward to carrying out Site Initiation Visits at Rotherham and York in March.

Queen Alexandra & Heartlands Hospital!



Milestones

36 patients recruited so far

26 sites open to recruitment

31 sites initiated to date

Investigator Meeting & Feedback

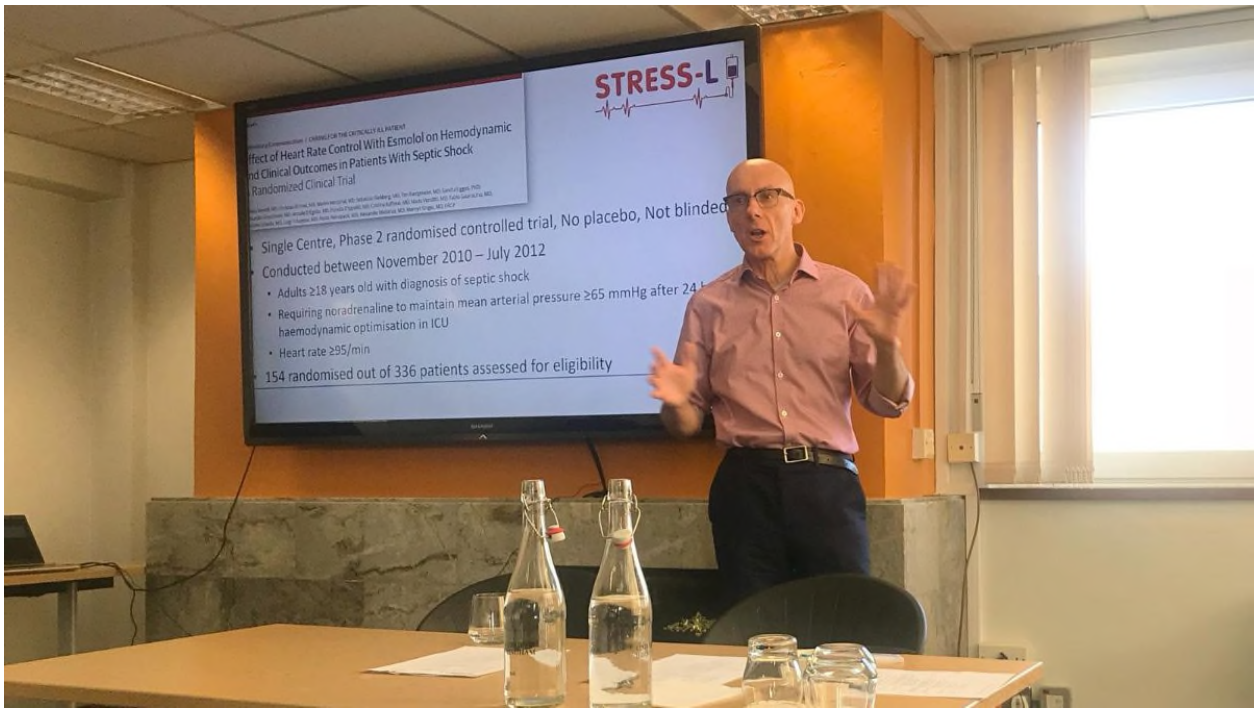
We had a brilliant time at our Investigators meeting at the University of Birmingham on Tuesday 5 March 2019. We really appreciate the effort and time take by sites to attend the meeting!

It was great to catch up with our sites in person and we hope you found the day as useful as we did. We would like to praise Colin Bergin from Queen Elizabeth Hospital Birmingham and Jung Ryu from University College Hospital London for sharing accounts of their personal experiences on the trial which were a great learning process for us all to understand the processes at site.

We would also like to thank Prof Mervyn Singer and AOP Orphan Pharmaceuticals for providing presentations on use of Beta Blockers in Septic Shock and a background to Landiolol. We found it interesting to hear about the progress of the similar Landi-Sep Trial being coordinated in Austria.

Please see below for valuable feedback on the breakout group sessions that took place during the meeting.

We would really appreciate your feedback on the Investigator Meeting via our Survey Monkey questionnaire:
https://www.surveymonkey.co.uk/r/VB2T5G6



Investigator Meeting Group Breakout Sessions Feedback

Please refer to our recently circulated feedback including presentation slides used during the meeting for full details. If you have not received this via email please contact the trial team. Below are some key learning points:

- **Feedback from clinicians regarding using beta blockers in septic shock has been positive. For AF patients, clinicians commonly use amiodarone as**

first choice and not beta blockade so this hasn't caused too many problems. PI's try to ensure equipoise is maintained and actively encourage clinicians to not use other beta blockade.

- **Landiolol Infusion protocol has been received well and clinicians have found the drug to be readily titrable.**
- **Active engagement and training ICU clinical team to assist with screening, recruiting and administering Landiolol to trial patients has been important to instil knowledge and confidence in clinical team regarding the trial.**
- **Keeping anticipated number of required vials locked in cabinet by patient's bedside with instructions for ICU nurse regarding how to prepare the drug has proved useful.**
- **The baseline research blood samples should be taken shortly after randomisation and before the landiolol infusion is commenced (if applicable). A good strategy for handling this busy period involves delegating responsibility for taking the baseline research blood sample to one team member and responsibility for preparing landiolol to another.**
- **As the trial is a complex CTIMP, we are unable to allow consent using local translation services, as any translations would have to be approved by the Ethics committee. If sites feel participant/relatives may have difficulty understanding the PIS/consent form, unfortunately they wouldn't be eligible for the trial.**

<u>WCTU Action Points:</u>

We will create a patient note sticker to indicate patient should not be administered any other beta blocker as randomised to STRESS-L.

We will look into creating video training tool for sites to train ICU clinical teams.

Data Management Update

Eligibility and Randomisation Forms

Following recent findings arising from routine central monitoring checks, all paper eligibility and randomisation forms will be requested by WCTU 24 hours post randomisation to ensure an appropriate member of delegated staff has completed these.

Please note: As per MHRA guidance for CTIMP's, eligibility must be assessed by a medically qualified clinician who has signed the paper eligibility form in addition to confirming eligibility in the patient's medical notes. Research Nurses should not be listed on the delegation log as responsibility for reviewing and confirming eligibility.

If consent from a professional legal representative is gained, this should again be performed by a medically qualified clinician; one who has ICU expertise but is independent from trial activity. If local NHS Trust policy permits, a research nurse can obtain consent from a patient or personal legal representative.

Cardiovascular & SOFA score forms

If no dose of a drug was received, please document **'O'** on the trial database rather than leaving the field blank. Similarly, for the Day 28 Follow Up form please state **'0'** for highest inotrope field if no inotrope was given.

Baseline Form

Please remember to document date and time of baseline ECG on the trial database. If an ECG was not done, please complete a protocol deviation form on and inform the trial team.

PI sign off

In order to streamline our processes, we will now request that the PI sign off form is completed at the end of the study, not after each participant. Therefore, **please wait until we request for these to be completed before sending to WCTU.**

Co-enrolment update

Please see below for our list of currently approved co-enrolling trials. Discussions are in progress with further studies but please let us know if there are any at your site which are a priority!

- A-STOP
- ADAPT-Sepsis
- BLING III
- FLO-ELA
- REST
- VACIRiSS

UKCCRG

The UK Critical Care Research Group are hosting their Twelfth national forum for clinical research in critical care, emergency medicine and acute medicine on:

Thursday 6 - Friday 7 June 2019 in Leeds

The STRESS-L Team are exploring the possibility of attending the meeting and hosting a drop-in Q&A session for all recruitment sites who will be in attendance. Please let the trial team know if you plan on attending this event to help us with planning.