STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade) Issue 6, Feb 2019 Newsletter

Site Set Up

The STRESS-L trial team hopes you are all having a great start to 2019. We experienced a strong end to the year with 4 patients recruited and 5 sites opened to recruitment in December; we would like to extend a warm welcome to Craigavon Area, Royal Devon & Exeter, Royal Liverpool, King's College, Royal Free and Peterborough City hospitals. We are looking forward to continued success in the New Year as we bring on board more centres.

ICS SOA 2018

Thanks to all who visited our research stand and mini investigators meeting at the ICS SOA conference in December. It was great to meet with you all to discuss trial updates and listen to your feedback. We hope you found it informative and we look forward to seeing you all again soon in Birmingham at our next Investigators Meeting.

Milestones so far

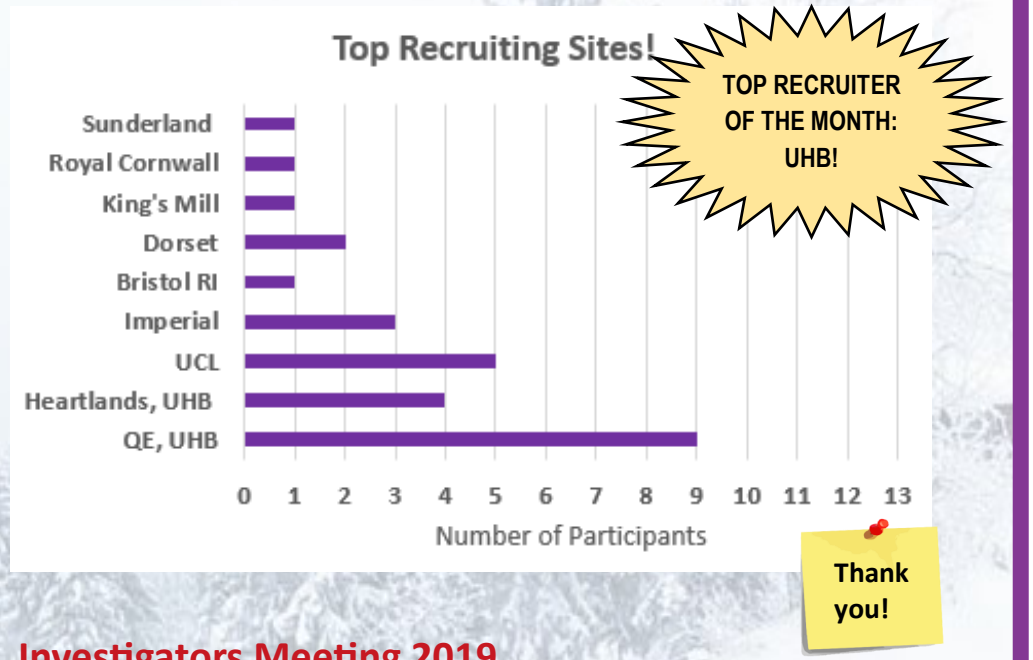
27 patients recruited so far

24 sites open to recruitment

30 sites initiated to date

Follow us on Twitter!

@StressLTrial



Investigators Meeting 2019

The STRESS-L investigators meeting will be held on Tuesday 5 March 2019, 10:00—16:00 at **Staff House in University of Birmingham**. Please let us know if you are able to attend by accepting the calendar invite and informing us of the nominated attendees. Travel costs will be covered for 2 representatives from each site. If you have any specific dietary requirements, please let us know. We look forward to seeing you!

Trial Team Update

We would like to give a warm welcome to Craig Turner (Trial Administrator) and Belinder Ghuman (Data Entry Clerk) who have recently joined the STRESS-L Team.

TRIAL UPDATES

Substantial Amendment

As you will know, substantial amendment 07 which includes Protocol v3.0, 18 Oct 2018 has recently received all regulatory approvals. **Please be aware this amendment requires local R&D approval before it can be implemented at your site.** The deadline for your local R&D to approve is: **7 Feb 2019.**

Please note alongside the updated protocol, the Patient and Legal Representative Information sheets and consent forms have been updated to Version 3.0, 18 Oct 2018. A **poster for relatives waiting rooms** has also been approved and is now available to use.

Protocol v3.0 18 Oct 2018—Key Changes:

Recruitment window

Vasopressor therapy window has increased from 48 to ***72 hours*** to allow greater flexibility for screening and recruiting participants, particularly over the weekend.

Advanced Liver Disease

Advanced Liver Disease exclusion criteria is measured by patients having a Child Pugh Score of ≥B.

Please note - a patient with acute liver ***failure*** may meet some of the Sepsis-3 criteria however, only patients who have septic shock treated with antibiotics for an infectious agent should be considered for the trial.

Restarting Landiolol

Landiolol infusion can recommence at **any point** whilst noradrenaline treatment continues and the patient remains tachycardic. Once the end of noradrenaline treatment visit has passed and the landiolol has been stopped for 12 hours or more, it should not be restarted.

Blood Sample Schedule

Optional PaxGene RNA biobank sample will now be collected at EONT alongside Day 0 and 1.

Co-enrolment

A co-enrolment agreement has now been finalised with VACIRiSS. Just as a reminder we also have co-enrolment agreements with REST, A-STOP and ADAPT-Sepsis. Please let us know if there are any other trials which are a priority for co-enrolment at your site.

Screening logs

Following feedback regarding the level of data collected during screening, we have streamlined the log to reduced burden and simplify the process. Rather than recording heart rate and noradrenaline timelines, our expanded reasons key will capture all the necessary information. Please add all future screened patients to **V6.0, 8 February 2019** of the log. Please get in touch if you have any queries.

Data Management

The STRESS-L Database is soon to be updated to add an additional field to the IN | OUT Fluids called 'Other' to capture TPN and IV Drugs (not diluted with Crystalloid). In the meantime, please keep a separate record of TPN and IV drugs for each record. Furthermore, please do not complete the e-CRF eligibility form as this requires an update to bring it in line with updated eligibility criteria listed in the current protocol. Please continue to complete the paper eligibility form (v3.0, 11 Jan 2019).

TRAINING MATERIALS

The following updated/new training slides have been issued:

Training for non-GCP delegated clinical staff (contain brief overview of key GCP principles. These slides are to be used for non-GCP trained medically qualified clinicians listed on the Delegation Log with the responsibilities E, F & K.

Training for ICU clinical staff. These slides can be used to train clinicians and nurses on ICU who are completely independent of the trial but may be involved in administering Landiolol and overseeing trial patients care.

Our FAQs document has also been updated recently to V2.0 24-Jan-2019.