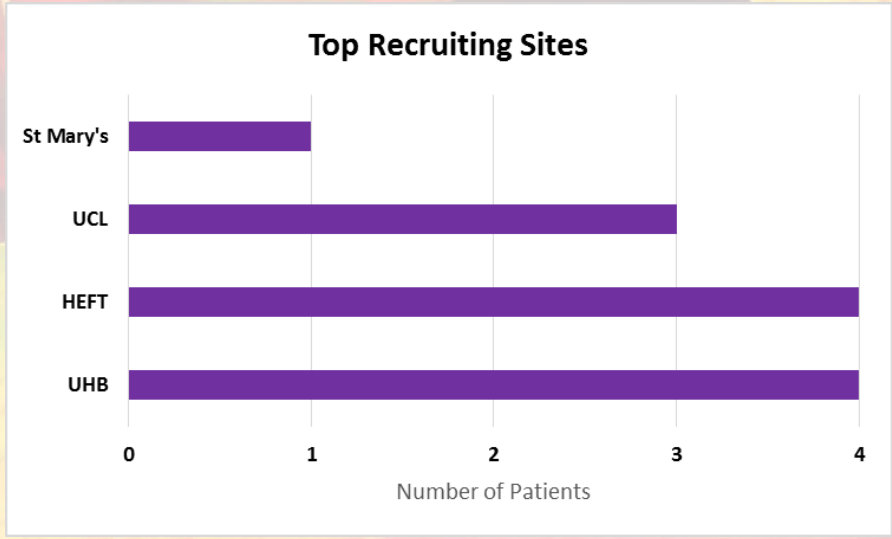
STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade). Issue 2, Sept 2018 Newsletter

Site Set Up

We would like to congratulate our centres for a successful and busy summer. The competition for our top recruiting site is strengthening with valuable contributions from all centres. Thank you all for your hard work and feedback.

We would like to give a special mention to Queen Elizabeth Hospital and Heartlands Hospital in Birmingham who have hit their yearly target of 4 patients within 5 months— a prize is on its way!

Since our last newsletter, Bristol Royal Infirmary and Nottingham have opened for opened for recruitment and we have visited Dorset County Hospital. Welcome to the trial! We have another busy month ahead with plans to visit Plymouth, Cornwall, Royal Devon & Exeter and Poole. We hope to update you on further sites in the next instalment.



Milestones so far

- 12 patients recruited so far
- 11 sites open to recruitment
- 12 sites initiated to date

Screening logs

Please remember to send in your screening logs (v1.1 04/Apr/2018) on a monthly basis to stress-l@warwick.ac.uk

Upcoming Events

Site teleconferences will be arranged in the near future giving sites the opportunity to share knowledge and ask questions.

We will get in touch soon to organise an open site teleconference. We hope to hold these sessions on a regular basis and intend for them to be used as a platform for all our recruiting centres to share knowledge, ask questions and suggest areas for improvement in an informal environment.

The STRESS-L team updates

Madeleine Flawn, Trial Coordinator, will be joining the STRESS-L Trial Team on Monday 10th September. Madeline will work alongside Johnny and Emma to deliver the trial and answer any questions you may have.

Please direct all correspondence to **STRESS-L@warwick.ac.uk** or call **02476 572 905.**

Eligibility

If the patient starts and restarts noradrenaline or another vasopressor therapy before the 24 hour mark or between 24 – 48 hours before they are randomised, when are they eligible for the trial?

If a patient is receiving vasopressor support for their septic shock and this stops for less than 12 hours before recommencing again this is counted as the same vasopressor episode. The 24-48 hour window will apply from when they first started receiving vasopressor support.

If the patient has a gap of more than 48 hours between the two episodes of vasopressor support because a new bout of septic shock has occurred, the 24-48 hour window will start at the beginning of the second episode.

If the scenario arises where the gap between the two episodes of vasopressor support is more than 12 hours but less than 48 hours, the trial team will need to be informed of this as these patients will be assessed on a case by case basis. 12 hours is commonly defined as the end of noradrenaline treatment and we predict this particular scenario is unlikely to occur.
Please contact the team to discuss these patients further.

Data Collection

Please ensure the cardiovascular daily data is continued to be collected past day 5 even if the patient has stopped Landiolol and Noradrenaline. Furthermore, just as a reminder, daily additional assessments are **not** required once the patient has stopped Landiolol and Noradrenaline.

Please keep an eye out for data query forms which will start to be distributed. Data queries are expected to be resolved and responded to within 2 weeks.

Please be aware of the critical expected data collection time points listed below:

Baseline, Participant and Confirmation of Eligibility forms	24 hours post randomisation date. In particular, if the date and time of noradrenaline or vasopressor support is missing or does not adhere with 24-48 hour recruitment window, the trial team will contact you immediately to confirm the patient's eligibility.
Daily Data	1 week post onset date.
Day 28 and 90 Follow up	1 week post onset date.

Updates

Substantial Amendment 05 - New Protocol

As you all are aware, the protocol has recently been updated following a substantial amendment to the trial. The amendment was required as a company called CSM Germany will now be labelling and packaging the IMP drug instead of Reig Jofre for the duration of the trial. Final QP release will be carried out by AOP. Mawdlseys in the UK will continue to distribute the drug to sites.

Please remember to adhere to v2.0 of our protocol dated 31 Jul 2018 and file this in section 2.1 of your Investigator Site File. For a summary of changes, please refer to the protocol version log issued on 17th August 2018.

Non-substantial Amendment 01 - GDPR changes

Due to the new General Data Protection Regulation (GDPR) regulation, our patient and legal representative information sheets have been updated. Please ensure that you use v2.1 dated 07 Jun 2018. Please continue to use v2.0 of our consent forms which remain unchanged. You can refer to the master documents version log issued on 17th August dated v2.3 17 August 2018 for a full updated list of all current documents for the trial.

Ambient Stock

Our current batch of IMP expires 30th September and we have fortunately managed to secure ambient IMP which has no special temperature storage requirements. The IMP will need to be stored in a secure location which can be either a locked cupboard or fridge.

We will get in touch to confirm details of the re-supply. The current batch will need to be quarantined 1 week before 30th September. We will provide an updated IMP Management Manual in the near future.