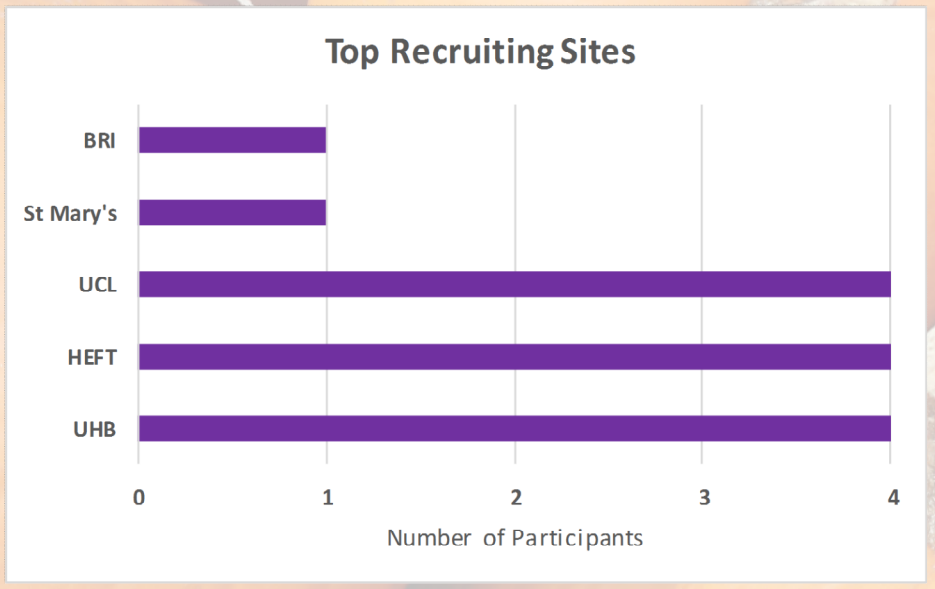
STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade) Issue 3, Oct 2018 Newsletter

Site Set Up

We would like to welcome Dorset County , Royal Cornwall and Poole Hospitals to the trial and extend a huge congratulations to Bristol Royal Infirmary who have recruited their first participant. Also, congratulations to UCL for recruiting their 4th patient meaning they have achieved their yearly target within 7 months! Please keep an eye out for some celebratory chocolates.

We are also very much looking forward to visiting Portsmouth, Sunderland Royal, Guy's & St Thomas' and Royal Liverpool over the next month.



Milestones so far

- 14 patients recruited so far
- 14 sites open to recruitment
- 18 sites initiated to date
- IMP ambient stock secured for remainder of trial

The STRESS-L team updates

Maddy Flawn, Trial Coordinator, has now joined the STRESS-L trial team. Maddy will work alongside Emma and Johnny to deliver the trial and answer any questions you may have.

✉ STRESS-L@warwick.ac.uk ☎ 02476 572 905

Screening logs

Following feedback we have decided to amend our screening log to capture the time of ineligibility prior to the 24—48 hour recruitment window as this will greatly help us to understand common time points for when patients become ineligible. Excluded due to co-enrolment issues as also been added to the screening log. Please refer to the key reasons and guidance tab of the spreadsheet for further details.

Please remember to send in your completed logs (v4.0, 04Oct2018) on a monthly basis to STRESS-L@warwick.ac.uk

Site Teleconference Feedback

Thank you to everyone who attended our first site teleconference session on Tuesday 2nd October. We hope you found the teleconference a valuable opportunity to share knowledge and speak with other sites to share tips and experiences of screening and recruitment. Minutes from the meeting have been circulated alongside a doodle poll for the teleconference which will take place in November. We will confirm the date and time for the next meeting shortly.

Blood Sampling Timelines

The blood sampling timelines were clarified as follows: Day 0 bloods should be taken close after randomisation with future samples taken in line with time of randomisation where possible, however, we understand that this is not always possible, for instance, where bloods are taken in the morning round.

Co-enrolment

Co-enrolment agreements will be pursued with a number of clinical trials including A-STOP, BLING III and TTM2. Please let us know if there are any other trials which are a priority at your site.

Whilst co-enrolment is not possible with the 65 trial, we confirmed that we are in the process of putting together a guidance document to assist with recruitment to both trials. Currently, those under the age of 65 should be considered for STRESS-L in addition to patients over the age of 65 who fail to meet the 65 trial eligibility criteria. For example, if a patient misses the 6 hour recruitment window for 65, they could then be considered for STRESS-L.

Trial Documents

As you will know V2.1 of the Consent Forms is now active—please ensure you are using the current version. A FAQ document will be circulated soon to offer additional guidance. We will also create a trial poster for ICU staff areas and look in to developing a poster to place in relative waiting rooms subject to ethical approval. Please let us know if you would like copies of either of these posters.

Updates

Ambient Stock

We successfully resupplied all sites with ambient IMP ahead of expiration of the previous cold chain stock at the end of September.

Just to remind you that this and all future IMP will have no special temperature storage requirements. The IMP will need to be stored in a secure location which can be either a cupboard or fridge. It is also acceptable to switch between room temperature and refrigerated without affecting the IMP's stability. In line with this supply change, the IMP management manual has been updated. The current version is V3.1 03 October 2018.

Please also make sure to send copies of your IMP inventory and destruction logs if you have not already done so.

Data Collection

Please keep an eye out for data clarification excel spreadsheet forms which will start to be distributed. Data queries are expected to be resolved and responded to within 2 weeks. It is expected that the baseline, participant and confirmation of eligibility forms will be entered within 24 hours of randomisation. All daily data forms are expected to be enter 1 week post onset date.

If no dose is given for a drug, please record '0' on the database rather than leaving a field blank. This will avoid data queries.

Oral fluids in includes nasogastric feeding. Please ensure to document the total fluids in and out.