STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade) Issue 4, Nov 2018 Newsletter

Site Set Up

The STRESS-L trial team has a had a busy month on the road visiting Portsmouth, Sunderland Royal, Guy's & St Thomas' and Royal Liverpool. Thank you all for your hospitality. We look forward to meeting the teams at Peterborough, Royal Free and King's College this month.

Since our last update, University Hospital Plymouth have opened and King's Mill have recruited their first participant!

Milestones so far

- **15 patients recruited so far**
- **15 sites open to recruitment**
- **20 sites initiated to date**
- **Successful Data Monitoring Committee held October 2018**

Site Teleconferences

Thank you to all who attended our first site teleconference session. Following feedback at the teleconference we have design a poster to place in ICU relatives waiting rooms which is pending HRA and ethical approval. We will keep you updated on when this poster will be available.

We will hold the next two sessions on the 08th and 13th November to share tips and your experiences.

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Screening logs

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

State of the Art Conference

The STRESS-L team will be attending this December's SOA conference in London and look forward to seeing many of you there.

We will be staffing a stand and holding an investigators meeting which is open to all to attend. We will provide full details once these are finalised.

Training sessions

A number of sites have fed back about how they have benefited from holding internal training sessions to spread awareness of the study throughout the clinical teams and how this has contributed to increased screening.

Sites have used a diverse array of methods including recording podcasts to circulate, holding informal coffee mornings and discussing the study at departmental meetings. We have non-research team training slides, eligibility laminates and infusion protocols which we can provide to assist you but please let us know if there are any further materials which we can prepare.

Data Collection

Death Notification

If a participant passes away in hospital, this will not be considered as a discharge and it will not be necessary to complete a hospital or ICU discharge form.

Likewise, if a participant passes away in hospital prior to Day 14, it will not then be necessary to complete a Day 28 Follow-Up Form as their mortality status and SOFA score data will be collected elsewhere on the e-CRF via the death notification form and daily data SOFA score form.

Fluid intake

Just as a reminder, oral fluids refers to **all** fluids that a patient intakes. Currently there is not a field where TPN and IV drugs can be captured. IV drugs can come under crystalloid **if** they have been diluted with a crystalloid solution.

Warwick's programming team plan to update the e-CRF in the new year to add an additional field under fluid intake called 'Other' to capture TPN and IV drugs. In the meantime, please can you keep a separate record of TPN and IV drug intake (if not diluted with crystalloid) for each patient and leave the field blank. Please inform the trial team of this to avoid us querying this data with you. Sorry for the delay and any inconvenience caused.

Updates

Co-enrolment

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

Trial Documents

As you will know V2.1 of the Consent Forms is now active—please ensure you are using the current version. The Master Documents Version Log has also been updated to V2.6 whilst we have also issued our Frequently Asked Questions document.

Blood sample storage logs

For monitoring purposes, please forward a copy of the blood sample storage logs after they have been fully completed for your first trial participant. This will only be required for the first participant unless the trial team deem further checks are necessary.

Trial Team Updates

Louise Clarkson, our site monitor, has now left her post in the Warwick QA team. Monitoring visits are currently on hold until a new monitor is appointed in the year . The visits will then continue to take place at sites after the first patient is randomised to Landiolol.