



STRESS-L: STudy into the REversal of Septic Shock with Landiolol (Beta Blockade). Issue 1, July 2018 Newsletter



Site Set Up

We have received a great deal of interest from sites across the UK and we would like to thank everyone for their support so far!

We have opened 9 sites to recruitment who have contributed greatly to our successful start. We would like to extend our gratitude to the teams at Heartlands, Royal Victoria Belfast, UCL, Imperial, King's Mill and Musgrove Park, in addition to our top recruiting site: University Hospital Birmingham!

We look forward to opening many more sites in the near future.

Milestones so far

- ◆ Full REC approval granted Nov 2017
- ◆ Attended ICS Conference Dec 2017
- ◆ Trial opened March 2018
- ◆ **First patient recruited April 2018!**
- ◆ 8 patients recruited so far
- ◆ 9 sites open to recruitment



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

Data Collection

- ◆ **When does Day 0 and Day 1 begin?**

Day 0 will begin **24 hours before the time of randomisation and end at the time of randomisation** (-24hrs – Time of randomisation). If you refer to the cardiovascular form, this may help to visualise the timeline.

Day 1 will begin at **the time of randomisation** so if a patient was randomised at 15:00 on the 2nd July, Day 0 will span from 15:00 on 1st July – 15:00 on 2nd July. Day 1 will begin at 15:00 on 2nd July and end 15:00 on 3rd July.

- ◆ **Should the worst or most recent data be collected for the SOFA score?**

Highest or lowest values over the 24 hour period will be collected meaning the worst score is collected and not the value closest to 24 hour mark.

An exception to this will be for certain variables which rely on blood test results which may be taken once a day; thus the one value for that day will be recorded. If blood tests are not routinely taken every day, the relevant variables can be left blank for that day.

A further exception to this is for the Other Outcome Data i.e. WCC, Delirium & CRP where the value will be as close as possible to the 24 hour mark at the end of the data collection day. Therefore, if a patient is randomised at 15:00 and assessment data is available at 11:00 and 14:00, the 14:00 data will be used.

- ◆ **What data is required until day 14?**

Daily SOFA score, cardiovascular and IN | OUT Fluid data is always collected up until day 14 unless the patient is discharged from ICU or deceases. Whilst Noradrenaline and Landiolol is still being administered, additional assessments are required including blood samples. After EONT and end of Landiolol, these assessments are no longer required.





◆ Does the IMP have special temperature requirements?

Currently our IMP stock is refrigerated and must be maintained within the temperature range of 2 - 8°C. However, from September we have secured an **ambient** IMP stock which has no special temperature storage conditions. We will advise sites closer to this time regarding restock.

◆ Is it permitted to administer beta-blockers in the control group?

As per the protocol, the control group will receive usual care and should not receive beta blockade whilst on ICU. If a clinical decision is made to administer beta blockers to control group patients, a **protocol deviation form** must be completed.

◆ Can ward nurses administer IMP?

The task of reconstituting IMP and preparing infusion can be delegated to the bedside nurse. However, research nurses must ensure sufficient oversight and a handover must be completed and documented in the medical notes. We encourage you to provide training to non-research colleagues and to raise awareness of the study, for instance through coffee mornings or staff facing posters. We can provide training slides, landiolol dosing charts and infusion protocols to assist you.

◆ Who is responsible for informing WCTU trial team when further IMP supply is required?

Pharmacy will be responsible for letting us know when you require re-supply as you will be holding the 2 back up boxes. Each time pharmacy release a box to ICU please email: stress-l@warwick.ac.uk . The research nurses will also take responsibility for this by informing us if there is a heavy patient requiring maximum dosage to bring this to our attention.

◆ Can bloods be taken on the weekend and left for processing on Monday?

No. It is expected a member of the research team or co-investigator will be available on the weekend to process the samples as they cannot be left. We expect only minimal weekend work will be required throughout the trial.

◆ Are all clinicians listed on the delegation log required to have GCP training?

Clinicians delegated responsibilities **E, F and K** on the delegation log are not required to carry out GCP training. However, they must sign the delegation log and investigator training log and read provided training slides created for non-research colleagues. Please contact the trial team to request these slides.



Paper CRF's

Please remember to send in paper copies of all paper Eligibility, Randomisation and End of Trial forms within 2 weeks of completion. These forms must be submitted via NHSmail as per our Data Transfer Working Instructions.

Blood Sample Storage Forms

Please remember to track all stored blood samples by completing the Sample Storage Form.

Enrolment and Pharmacy ID logs

Please remember to update your ISF Enrolment Log and Pharmacy ID logs. We have updated the Pharmacy ID Log to v2.0 dated 18/July/2018 which can be completed using information provided in the randomisation confirmation emails.

The STRESS-L team updates

We are sad to say that Nafisa Boota has now left her post in the trial. We thank her for all her hard work on the trial and wish her all the best in the future.

Emma Skilton has replaced Nafisa as Trial Manager.

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