**Guck, Jonathan**

**From:** STRESS-L, resource
**Sent:** 09 May 2019 09:47
**To:** Guck, Jonathan
**Subject:** FW: STRESS-L May 2019 Newsletter

# STRESS-L May Newsletter, Issue 8


@StressLTrial  Trial Website

**Welcome to the new email format of the STRESS-L Newsletter which we hope is more accessible! Please let us know if you have any suggestions for improvements or information you would like to see included on a monthly basis.**

**Please click on the headers below which will take you to the different sections.**


## Care Withdrawal Guidance

Patients should not be recruited if a withdrawal of care decision is in place or imminent. HOWEVER, as the target population under study are very sick (don't forget Morelli's [JAMA, 2013] population had a mortality of 80%!), patients should be considered for a trial where a withdrawal of care decision is not in place.

# Trial Update

The STRESS-L trial team would like to welcome Warwick, Rotherham York and Buckinghamshire Hospitals to the trial! Thank you for your engagement throughout site set up and we are looking forward to working with you over the months ahead. We have also had a busy spell with 5 patients recruited in the last 10 days - well done!

Although research is sometimes stressful, we hope you had a great, relaxing bank holiday weekend and if you need any help to decompress maybe our STRESS-balls can help! Please let us know know if you would like to receive some.

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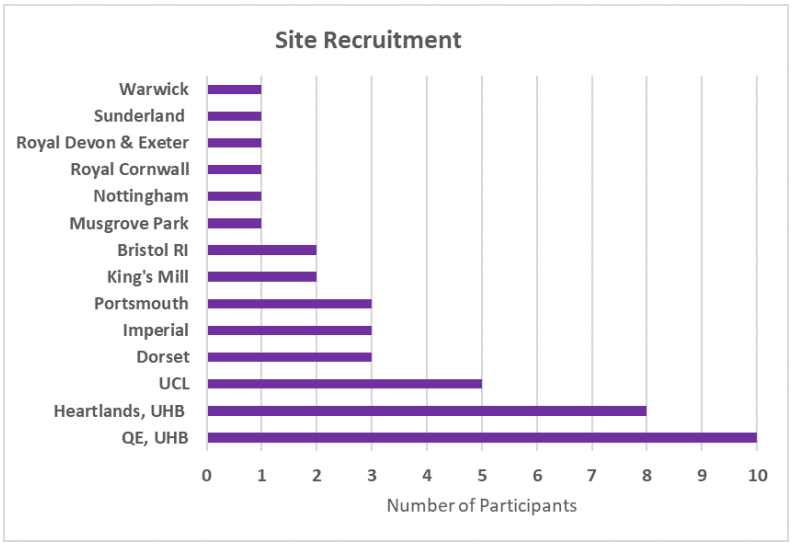
**Queen Elizabeth, UHB**

Congratulations for recruiting your **10th** patient!




## Milestones

**42** patients recruited so far

**29** sites open to recruitment

**31** sites initiated to date

# Data Management Update

An error has recently been highlighted on our paper CRF. Just to clarify that the units for landiolol administration are mcg/kg/min, NOT ml/hr. This has been corrected in CRF V5.0 18-Apr-2019. Please let us know if any previous data entry has been affected.

The CRF Completion Guidelines (V2.2 18-Apr-2019) and Master Documents Version Log (3.5 18-Apr-2019).

## Eligibility and Randomisation Forms

Following recent findings arising from routine central monitoring checks, all paper eligibility and randomisation forms will be requested by WCTU 24 hours post randomisation to ensure an appropriate member of delegated staff has completed these.

**Please note: As per MHRA guidance for CTIMP's, eligibility must be assessed by a medically qualified clinician who has signed the paper eligibility form in addition to confirming eligibility in the patient's medical notes. Research Nurses should not be listed on the delegation log as responsibility for reviewing and confirming eligibility.**

If consent from a professional legal representative is gained, this should again be performed by a medically qualified clinician; one who has ICU expertise but is independent from trial activity. If local NHS Trust policy permits, a research nurse can obtain consent from a patient or personal legal representative.

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## Cardiovascular & SOFA score forms

If no dose of a drug was received, please document **'0'** on the trial database rather than leaving the field blank. Similarly, for the Day 28 Follow Up form please state **'0'** for highest inotrope field if no inotrope was given.

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## Baseline Form

Please remember to document date and time of baseline ECG on the trial database. If an ECG was not done, please complete a protocol deviation form on and inform the trial team.

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## PI sign off

In order to streamline our processes, we will now request that the PI sign off form is completed at the end of the study, not after each participant. Therefore, **please wait until we request for these to be completed before sending to WCTU.**

# Adverse event reporting

Please remember to document any adverse events on the adverse events form.

The following events are exempt from adverse event reporting AND serious adverse events as well as SUSAR's and SAR's UNLESS the investigator deems the event to be related to the administration of the study drug:

- Death Related to sepsis
- Cardiovascular failure, including the need for vasopressors / inotropes
- Respiratory failure, including mechanical ventilation and acute lung injury
- Hepatic impairment as measured by Transaminases <1000 IU/L
- Renal failure, including the need for renal replacement therapy
- Haematological / Coagulation failure, including thrombocytopaenia and disseminated intravascular coagulopathy
- Delirium / confusion

If an event occurs which is **not** included in one of the above outcomes, this must be reported as per safety reporting definitions. For example, if a patient has pyrexia and this is not related to the drug and not serious, this must be reported as an adverse event. Even though Pyrexia is expected in some cases to occur due to Sepsis, it should still be reported.

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# Co-enrolment update

Please see below for our list of currently approved co-enrolling trials. Discussions are in progress with further studies but please let us know if there are any at your site which are a priority!

- A-STOP
- ADAPT-Sepsis
- BLING III
- FLO-ELA
- REST
- VACIRiSS

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# UKCCRG

The UK Critical Care Research Group are hosting their Twelfth national forum for clinical research in critical care, emergency medicine and acute medicine on:

**Thursday 6 - Friday 7 June 2019 in Leeds**

The STRESS-L Team will be hosting a presentation at **12:30 - 13:00** on **Friday 07th June** for all current and upcoming sites who will be in attendance. We hope to see you there!