

Guck, Jonathan

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Issue 15



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Trial Update

STRESS-L has started the decade strongly with a phenomenal month of recruitment! **12** patients were recruited in January from **10** sites - our highest ever month.

Since our last newsletter we have welcomed Brighton and Sussex to the study and look forward to opening further sites throughout February.



We have now reached **99** recruits! Well done to everyone for managing a very busy period in critical care. Who can get number **100**?!

Milestones

99 patients recruited so far

36 sites open to recruitment

39 sites initiated to date

08/11/2019 Successful DMC Meeting held

12/12/2019 Successful TSC Meeting held



Learning Corner

Blood sampling timelines

As we have had a few instances where the blood sampling schedule has gone amiss, please see below for a summary of the collection schedule and please get in touch if you have any queries. Please note - blood samples should be obtained for both standard care and landiolol patients! Unlike Data Entry, blood samples will be collected in calendar days.

	Day 0/Baseline	Day 1	Days 2, 4 and 6	EONT
What time frame is this?	Immediately after randomisation (or before if consent has already been granted)	Day 1 = Time of randomisation up to +24 hours	Day 2 = T +24 hrs – T +48 hrs Day 4 = T +72 hrs – T +96 hrs Day 6 = T +120 hrs – T +144 hrs	EONT = 12 hrs after Noradrenaline treatment stops
What needs to be taken?	3 x Green Lithium Hep 1 x PaxGene RNA 1 x PaxGene DNA	3 x Green Lithium Hep 1 x PaxGene RNA	3 x Green Lithium Hep	3 x Green Lithium Hep (do not take if these have already been taken due to EONT falling on a sampling day ie. Day 1, 2, 4 or 6) 1 x PaxGene RNA
Time it should be taken in?	As soon as possible – and before Landiolol infusion starts for those in the Landiolol arm	Anytime within the 24 period , but ideally towards the end so that there's some separation from the baseline bloods	Anytime within the designated 24 period	EONT occurs when Noradrenaline is stopped for 12 hours or more. Samples must then be taken within 24 hrs of EONT

End of Noradrenaline Treatment time point

Please be aware that the EONT time point will be triggered once noradrenaline treatment has ceased for 12 hours. For instance, if Noradrenaline treatment stops at 10:00 and remains off for at least 12 hours, the EONT time point will be triggered at 22:00. The End of Noradrenaline Form will capture the date and time that Noradrenaline was discontinued for 12 hours - from the above example this would be 22:00.

Once triggered the time of the EONT will not change **even** if Noradrenaline treatment re-starts after the 12 hours, or if it is expected that treatment will recommence soon after the 12 hours.

Consent Workshops

As we appreciate that seeking consent in a critical care environment and from patients who

lack capacity can pose challenges, we are in the process of organising two consent workshops to be held on: **09th March** 11:00 - 13:30 and **17th March** 14:00 - 15:30.

These sessions will be cross-trial and will be structured in a way to give our critical care teams the forum to discuss common issues and share best practise tips with research nurses at sites offering personal accounts of how they have approached seeking consent in difficult circumstances. Please refer to our recent email to see the proposed agenda and look out for our upcoming email with dial in details.

Recruitment Case Study

Do you keep on screening and wondering when your first patient will come along?...

It can seem that the patients who are eligible for STRESS-L are rare and sporadic which is why regular, reliable screening is of such importance.

This is well demonstrated by Derriford Hospital where the team **struggled to see any eligible patients within their first 14 months of recruitment**, however, their persistence with daily screening and clinical support has paid off with their first **2 participants recruited in January.**

Hard work, patience and some luck pay off in the end!

Sepsis in the News

The work you are doing is helping in the fight against sepsis, a pressing issue both in the UK and worldwide.

A recent study published in the Lancet showed that 20% of all global deaths were sepsis related. Please see below for further info:

<https://www.bbc.co.uk/news/health-51138859>

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)32989-7/fulltext?rss=yes](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32989-7/fulltext?rss=yes)

Out of Hours Emergency Phone Line

The STRESS-L trial team at Warwick CTU can now be contacted via the following telephone number for any **emergency queries** during evenings and weekends: **07385 029 213**

Please be aware this number should only be used for emergency queries and questions which require an immediate response.

Normal working hours

Please continue to contact the trial team via the following office telephone number and email during normal working hours Monday - Friday: **02476 572 905**; stress-l@warwick.ac.uk

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**
- **CRYOSTAT-2**
- **EFFORT**
- **FLO-ELA**
- **GenOMICC**
- **PHIND**
- **PQIP**
- **REST**
- **STARRT-AKI**
- **TAME**
- **TARDIS**
- **UK-LVR**
- **VACIRiSS**