RECOVERY-RS
RESPIRATORY SUPPORT

RECOVERY-RS Group site teleconference
21 & 28 September 2020

Contents

ATTENDEES

NAME	Trial team	DATE
Professor Danny	Co-CI	21.09.2020 & 28.09.2020
Professor Gavin Perkins	Co-CI	28.09.2020
Scott Regan	SPM	21.09.2020 & 28.09.2020
Emma Skilton	Trial Manager	21.09.2020 & 28.09.2020
Nicola McGowan	Trial Manager	21.09.2020 & 28.09.2020
Professor Paul Dark	Co-investigator & Salford Royal PI	21.09.2020 & 28.09.2020
NAME	**SITE/CRN**	**DATE**
Lynne Keogan	Aintree	21.09.2020
Nassa Heeam	Aneurin Bevan	21.09.2020
Yogini Raste	Croydon	21.09.2020
Osei Kankam	East Sussex	21.09.2020
Tabitha Skinner	Homerton	21.09.2020
Michael Crooks	Hull	21.09.2020
Susannah Bloch	Imperial	21.09.2020
Michael Steiner	Leicester	21.09.2020
Alison McMillian	Lister	21.09.2020
Patricia Cochrane	NHS Fife	21.09.2020
Amanda McGregor	NHS Fife	21.09.2020
Fiona Adam	NHS Fife	21.09.2020
Joanna Matheson	NHS Highland - Raigmore Hospital	21.09.2020
Fiona Barrett	NHS Highland - Raigmore Hospital	21.09.2020
Jocelyn Keshet-Price	Norfolk and Norwich	21.09.2020
Anna Morley	North Bristol	21.09.2020
Liaquat Ali	Northern Lincolnshire & Goole	21.09.2020
Dorothy Hutchinson	Northern Lincolnshire & Goole	21.09.2020
Saima Ashraf	Nottingham University Hospitals	21.09.2020
Pamela Bradley	Pennine	21.09.2020
Jessie Wellbourne	Plymouth	21.09.2020
Karen Rudge	Plymouth	21.09.2020
Colin Wells	Plymouth	21.09.2020

Ethel B	Royal Marsden	21.09.2020
Marie Green	Royal Wolverhampton	21.09.2020
Charlotte Caroline	South Tyneside and Sunderland	21.09.2020
Joan Redome	Torbay	21.09.2020
Shruthi Konda	West Hertfordshire	21.09.2020
Brett Pereira	William Harvey	21.09.2020
Manish Patel	Wishaw	21.09.2020
Harsha Reddy	Wrexham Maleor	21.09.2020
Xavier Bindhu	Wythenshawe	21.09.2020
Christopher Carlin		21.09.2020
Janet Marrs		21.09.2020
Nita Sehgal	North Manchester, Pennine	28.09.2020
Heeam Nassa	Aneurin Bevan	28.09.2020
Richard Turner	Charing Cross	28.09.2020
Seonaid	CRN	28.09.2020
Debbie Campbell	CRN Eastern	28.09.2020
Charlotte Gosden	CRN Kent, Surrey & Sussex	28.09.2020
Dean Phillips	CRN North East and North Cumbria	28.09.2020
Chrisotpher Levett	CRN South West Peninsula	28.09.2020
Jacqui Dooley	CRN Yorkshire and Humber	28.09.2020
Carina Cruz	East & North Herts	28.09.2020
David Loader	East Kent	28.09.2020
Jay Naisbitt	Fairfield General	28.09.2020
Hamish McAuley	Glenfield	28.09.2020
Martina Marotti, Aneta Bociek, Rosie	Guys and St Thomas	28.09.2020
Mary Bellamy	Heartlands	28.09.2020
Tabitha Skinner	Homerton	28.09.2020
Stephanie Bell	Ipswich	28.09.2020
Alison McMillan	Lister	28.09.2020
Laura Adams	Medway	28.09.2020
Laura Adams	Medway	28.09.2020
Gabriel Claire	Mid Cheshire	28.09.2020
Katherine Pagett	Mid Cheshire	28.09.2020
Claire Gabriel	Mid Cheshire	28.09.2020
Sarah Francis	Newcastle Hospitals	28.09.2020
Sarah Francis	Newcastle Hospitals	28.09.2020
Dorothy Hutchinson	Northern Lincolnshire & Goole	28.09.2020
Rupani Hitasha	Portsmouth	28.09.2020
Debbie Campbell	NHS Highland, Raigmore Hospital	28.09.2020
Olly Hamilton	Royal Liverpool	28.09.2020
Hassan Burhan	Royal Liverpool	28.09.2020
Karen Williams	Royal Liverpool	28.09.2020
Ellie Traverse	Russells Hall	28.09.2020
Ellie Traverse	Russells Hall Hospital	28.09.2020
Ahmed Zaki	Stockport	28.09.2020
Roxana Stanciu	Stockport	28.09.2020
Lou Anning	Torbay	28.09.2020

Atwal Inderjit	Warwick	28.09.2020
Sally Humphreys	West Suffolk NHS Foundation Trust	28.09.2020
Arnold Dela Rosa		28.09.2020

SITE AND RECRUITMENT UPDATE

- 185 patients recruited & 73 sites open as of 28/09/2020. As of 03/11/2020 328 patients recruited. 33 sites have recruited. As of 03/11/2020 41 sites have recruited.
- 22 patients recruited in September which is the highest number of recruits within a month since June.
- Majority of recruitment from West Midlands (33%), Greater Manchester (25%) and East Midlands (10%)
- During the summer we have seen a decline in COVID-19 cases and eligible patients receiving non-invasive oxygen support for inclusion in the trial however, a second wave is now on the horizon with numbers increasing.

Experiences of running the trial at site

Heartlands & Good Hope: Prof Gavin Perkins (co-CI) & Mary Bellamy (Research Nurse)

- During the first wave, the Heartlands team established ward based CPAP delivery using provided UCL Ventura CPAP devices as the critical care service were overwhelmed.
- Respiratory physicians aided recruitment in the first wave and were able to train ward staff.
- Patients are managed in AMU at Good Hope where they are very well set up to deliver HFNO so have continued with this service with physicians leading recruitment.
- This ward was closed down as COVID cases decreased.
- Patients were then transferred to critical care for CPAP/HFNO as this intervention was not ward based.
- COVID ITU cases have creased but over the last week haven encountered oxygen flow challenges therefore Heartlands now considering ward based CPAP service again. The respiratory physicians who assisted in the first wave have now returned to normal duties therefore a mixed team of people is being used to help manage delivering the interventions on the ward again.
- Trial recruitment is led by the infectious diseases department in liaison with the research teams. Effective systems have been established and are in place.

Fairfield General: Dr Jay Naisbitt (PI)

- The trial has been successfully integrated within the local clinical pathway of care with help from respiratory unit.
- There was an initial bias CPAP was superior but experiences have shown patients receiving standard care on 15 litres of oxygen have achieved good outcomes.
- This trial is critical to find which respiratory support method is best as we still do not know.
- The consent model has been particularly useful as many patients don't have capacity and the deferred consent model facilitates quick randomisation.

KEY MESSAGES

In recent weeks the trial team have received feedback from sites regarding managing the local implementation of the trial in to their clinical pathway and ongoing equipoise challenges. With this in mind, Professor Danny McAuley (co-CI) led a feedback session with the resulting key messages:

1. **Recruitment will continue to all 3 arms for now.** The trial design is pragmatic and flexible to allow for randomisation to CPAP vs Standard Care or HFNO vs Standard Care depending on availability of each intervention that day.

2. **The next interim analysis will take place in December when 430 patients have been recruited.** The continuation of recruitment to all 3 arms will be reviewed to assess the potential of dropping an arm if required.

3. **There is still uncertainty regarding the benefits and harms of both HFNO and CPAP with conflicting international guidelines**. **Clinical equipoise is essential** to help resolve doubts around effective respiratory support treatments for COVID-19 patients. If you have significant concerns regarding maintaining equipoise with cross over of intervention occurring frequently please contact recovery-rs@warwick.ac.uk

4. **Consider altering clinical pathways to capture patients earlier on** e.g. in A&E as later on they may have escalated requiring ventilation or alternatively improved therefore they no longer meet the oxygen inclusion criteria.

5. **If a patient is receiving a trial intervention for a short period prior to randomisation, they might be considered for randomisation.** Please contact the trial team to discuss these patients on a case by case basis as we must ensure equipoise will be upheld.

6. **Encourage collaboration between respiratory (pre ICU ward based trial), ICU and wider teams** to maximise recruitment opportunities and support available.

7. **Embed RECOVERY-RS in to local clinical pathways** and SOPs. Please see Fairfield General Hospital's SOP example.

8. If possible, **create a dedicated ward area** to deliver CPAP and HFNO with trained nurses to avoid escalation to ICU.

9. Recruitment to RECOVERY-RS as an Urgent Public Health trial is still of upmost importance and if you are struggling with support & capacity during the second wave please contact recovery-rs@warwick.ac.uk

SITE FAQ'S

Q: If a patient is receiving high flow oxygen via a face mask is this still classified as HFNO?
A: If a patient is receiving >30 litres of high flow oxygen via a face mask using a specialist device such as AIRVO this will be classified as HFNO. If the patient is receiving less than 30 litres of oxygen this is not classified as a High Flow rate.

Q: Sometimes clinical teams will frequently switch between both CPAP and HFNO if the patient is eating/drinking or not tolerating one as well. Is this allowed?
A: We understand bridging to intubation may result in use of CPAP and HFNO and we recognise this may occur. Where possible crossover of treatment should be avoided. If a patient is having a short break from one of the trial interventions to eat/drink this is acceptable.

Q: Has there been issues implementing HFNO at other sites?
Concerns have been previously raised. As with CPAP, HFNO is aerosol generating, and if patients are receiving these treatments this should be in the setting of PPE usage. However, if sites cannot, or do not wish to, provide HFNO, it is still possible to participate in the trial by enrolling to the standard care vs. CPAP arm, as our randomisation system accommodates for when only one of the interventions is available.

Q: Not all sites within high recruiting regions are recruiting patients. Why is this?
Linking up ICU, respiratory and research teams is critical for success. Embedding RECOVERY-RS in to the clinical pathway has been essential for Fairfield General explains PI Jay Naisbitt. Some sites have struggled with patients going straight to CPAP and there being a lack of a dedicated ward area to deliver the interventions with trained respiratory nurses. Also to note is not all sites are open within each region.

Q: Is it possible to investigate a cohort of patients who are not for intubation to identify whether CPAP or HFNO is superior?
A few attendees in support of this but this is not currently something we will incorporate within RECOVERY-RS as it is a separate research question.

Q: Is it possible to investigating proning of patients?
Proning of patients should be considered standard care but is allowed across the treatment arms. There is no evidence yet on its efficacy. May potentially add proning as additional arm in the future but no plans yet.

Q: If a patient is subsequently found to not have covid should they be included?
Yes. It is an intention to treat protocol and this also reflects real life with COVID testing in a

NHS setting. Suspect COVID patients will be analysed and a sensitivity analysis will be performed to exclude confirmed non-COVID patients.

REMINDER: Please complete patient's ethnicity data on e-CRF as soon as possible as BAME data is submitted to NIHR on a weekly basis every Friday as a high priority.

Thank you to all of our sites and those involved for your hard work and dedication to RECOVERY-RS. It is greatly appreciated.