RECOVERY-RS
RESPIRATORY SUPPORT

Substantial amendment: #1
Submission date: 21-04-20
REC Approval date: 21-04-20

Protocol v3 21-02-20

Main amendments

- Consent process updated to enable consent prior to enrolment where patient has capacity
- Eligibility criteria update to clarify that patients will be eligible with FiO2 more than or equal to 0.4 and SpO2 less than or equal to 94%. (IRAS A17-1)
- Updates to protocol to include Scottish specific processes as appropriate
- All changes are referenced in full below

Full list of Amendments

- Clarification of resource account details throughout (recovery-rs@warwick.ac.uk)
- Trial summary: Update to the Trial Title: RECOVERY-RS Respiratory Support: Respiratory Strategies in COVID-19; CPAP, High-flow, and standard care
- Updates throughout to reference that the trial will also be open in Scotland (section 1.5, 2.1) IRAS Filter Question 3, A6.2, A30-1, A40, A50, A71-2, A72 and B11
- Section 1.5 – update to reflect the consent procedures in England, Wales and Northern Ireland (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11) and updated to include Scotland.
- Figure 1 – updated to include consent possible after screening
- Section 2.4.1 – updated to reflect appropriate data linkage (IRAS A6-2) and that ethnicity as well as all-cause mortality will be collected via data linkage
- Section 2.4.1 – addition of secondary outcome 'duration of invasive ventilation' (IRAS A-11)
- Section 2.5.1 – clarification that patients will be eligible with FiO2 more than or equal to 0.4 and SpO2 less than or equal to 94%. (IRAS A17-1)
- Section 2.8 – Section updated to include Scotland consent processes. England, Wales and Northern Ireland section amended to reflect new consent approach in these nations (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11)
- Table 1 – updated to reflect amended consent approach in England, Wales and Northern Ireland. (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11)
- Section 2.9.1 – reference to online randomisation removed and inclusion of the interactive voice response system. (IRAS A-61)
- Section 2.10.1 – clarification of initial CPAP settings that are being collected on the CRF. (IRAS A-13)
- Section 2.10.2 – clarification of the initial HFNO settings that are being collected on the CRF. (IRAS A-13)
- Section 2.11.2 – removal of reference that CTU staff will be blind to the study arm
- Table 2 – removal of Visit 2 Day 2 for clarity for sites.
- Section 4.1.1 – deletion of AE 'hypercapnia' and inclusion of 'respiratory acidosis with pH <7.25 prior to intubation
- Sections 4.1.3, 4.1.4 and 4.2 – clarification added to the SAE review process
- Section 5.1 – Detail added to clarify the data collected following randomisation. Clarification that ethnicity and mortality will be collected via data linkage. Updated to reflect appropriate data linkage across the devolved nations. Reference to onsite monitoring removed.

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- Section 6.2 – removal of detail regarding interim analyses and inclusion of reference to statistical analysis plan for formal stopping rules.

RECOVERY-RS Patient Information Sheet v3.0 20-Apr-2020
RECOVERY-RS Short Patient Information Sheet v3.0 20-Apr-2020
RECOVERY- RS Assent Form v3.0 20-Apr-2020
RECOVERY-RS Consultee Consent Form v2.0 20-Apr-2020
RECOVERY-RS Consent Form Deferred Consent v2.0 20-Apr-2020
Amendments:

- Updated documents to include reference to collection of race and ethnicity data.

RECOVERY-RS Consent Form on Commencement V1.0 20-Apr-2020
RECOVERY- RS PIS on Commencement V1.0 20-Apr-2020
RECOVERY-RS Short PIS on Commencement V1.0 20-Apr-2020
Amendments:

- New information sheets and consent forms for obtaining verbal informed consent from patients with capacity, prior to randomisation.