REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

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17/12/21
Re: Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community - Acquired Pneumonia
REC reference: 18/lo/0660
EudraCT number: 2015-002340-14
IRAS project ID: 237150

Substantial amendment 32 (AM032) Expedited Approval
I am submitting substantial amendment AM032 for the REMAP-CAP study.
This involves:
The reopening of the immunoglobulin domain with new interventions
The addition of the Monoclonal Antibody Domain

The addition of the Monoclonal Antibody Domain
Monoclonal Antibody Therapy (additional samples)
Casirivimab and Imdevimab are neutralising monoclonal antibodies that have been shown to bind to SARS-CoV2 virus, blocking its entry into the body's cells, reducing the virus' effects.
The interventions available are:
1.2g casirivimab / 1.2g imdevimab (low dose)
4g casirivimab / 4g imdevimab (high dose)

This study is taking into account evidence derived from other clinical trials, and a UK wide policy that recommends the use of low dose casirivimab /imdevimab for use in patients hospitalised due to COVID-19 and have blood tests that show, they do not have antibodies against SARS-CoV-2. We are comparing the effects of low dose compared to a higher dose. Additional samples will be collected as part of this domain. These samples will be transported to a central laboratory for testing. All samples collected under this study will be used within this study or in other ethically approved studies. The 1st sample will be taken with 24hours of the treatment being completed, one sample between days 3 and 7 and one sample between days 7 and 14. We will take a final sample between says 14 and 28 if the participant is still in hospital. Each blood sample will take up to 6mls (2 teaspoons or less).

The reopening of the immunoglobulin domain with new interventions
Immunoglobulin; Convalescent Plasma Therapy (additional samples)
COVID-19 immunoglobulin therapy is a blood-based treatment, giving patients antibodies to help fight infection. Antibodies are found in plasma, which is the liquid part of blood. It contains a mixture

of proteins including antibodies, clotting factors, and natural anticoagulants. Convalescent plasma is plasma collected from volunteers who have recovered from COVID-19, which contains antibodies to help fight COVID-19.
The interventions available are:

No Immunoglobulin Therapy (no placebo)
High Titre Convalescent Plasma

This study is taking into account evidence derived from the results from the 1st stage of this domain in REMAP-CAP, as well as other clinical trials. There are a significant number of patients with an impaired immune system who would be eligible to be included within this trial and may benefit from this intervention. This population of patients are potentially also less likely to respond to COVID-19 vaccinations and are therefore more at risk of COVID-19 disease. Additional samples will be collected as part of this domain. These samples will be transported to a central laboratory for testing. All samples collected under this study will be used within this study or in other ethically approved studies. We will take blood and respiratory samples from participants on entering the study and then a single respiratory sample each week until hospital discharge. The blood sample will take up to 15mls (3 teaspoons or less).
Patients would only be randomised to these treatments if participants have acute illness due to confirmed COVID-19 and are immunosuppressed at the time of eligibility.

I have also made the below changes to the MHRA CTA.
casirivimab / imdevimab (Ronapreve)

I have also updated the participant information sheets to add the new interventions and domains

Documents submitted as part of Substantial amendment AM030:
REMAP-CAP - Monoclonal Antibody DSA V1 22 November 2021
REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 29 November 2021 CLEAN
REMAP-CAP COVID-19 Immunoglobulin Therapy Domain-Specific Appendix V3 - 24 November 2021_TC from V1.01
REMAP-CAP Amendment_Tool_AM32_20211217

revised-gb-spc-ronapreve-clean-120mg-ml12aug2021docx

Brief REMAPCAP ProLR_IS summary v5 261121 TC
Brief REMAPCAP ProLR_IS summary v5 261121 CLEAN
UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland TC
UK REMAP CAP COVID19 PerLR ICF V1.9 2021.11.26 Scotland CLEAN
UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI TC
UK REMAP CAP COVID19 PerLRIS ICF v1.10 2021.11.26 NI CLEAN
UK REMAP CAP COVID19 PerLRIS ICF v1.11 2021.11.26 TC
UK REMAP CAP COVID19 PerLRIS ICF v1.11 2021.11.26 CLEAN
UK REMAP CAP COVID19 PIS ICF V1.9 2021.11.26 Scotland TC
UK REMAP CAP COVID19 PIS ICF V1.9 2021.11.26 Scotland CLEAN
UK REMAP CAP COVID19 PIS ICF V1.10 2021.11.26 NI TC
UK REMAP CAP COVID19 PIS ICF V1.10 2021.11.26 NI CLEAN
UK REMAP CAP COVID19 PIS v1.11 TC
UK REMAP CAP COVID19 PIS v1.11 CLEAN
UK REMAP CAP COVID19 Retro PIS ICF V1.9 2021.11.26 Scotland TC

UK REMAP CAP COVID19 Retro PIS ICF V1.9 2021.11.26 Scotland CLEAN
UK REMAP CAP COVID19 Retro PIS ICF V1.10 2021.11.26 NI TC
UK REMAP CAP COVID19 Retro PIS ICF V1.10 2021.11.26 NI CLEAN
UK REMAP CAP COVID19 Retro PIS ICF v1.11 2021.11.26 TC
UK REMAP CAP COVID19 Retro PIS ICF v1.11 2021.11.26 CLEAN

Many Thanks
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