PROTECT V (CPMS ID: 47409; EudraCT:2020-004144-28)
Frequently Asked Questions
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Study team contact details	
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SITE IDENTIFICATION	
Is there a minimum recruitment target for the study per site?	No, but be aware that payments will be done every 10 randomised participants to encourage recruitment. Global recruitment goal is 1500 randomised participants
Is there HRA/REC approval for the participation of our site in the trial?	As a COVID trial, PROTECT was submitted with provision to add as many sites as needed without an amendment to HRA/REC. This can be checked in the following documents: IRAS Form section A72 had “Others” marked and “All UK NHS hospital/healthcare facilities” in the free text, this is indicated in the third paragraph of the REC cover letter at submission and HRA acknowledges this at the end of the initial approval letter
Due to the structure of our trust and our onsite dialysis units belonging to other trusts, we do not have access to dialysis patients. Would we be able to still run the study without the dialysis patient population (i.e. just look at recruiting	**Yes, we are happy to activate sites as long as they have access to at least one of the trial populations**

from the other 2 patient populations)	
Will sites need to indicate and be activated for each participant population or is one approval enough for all populations?	**Single approval process sites can activate any group of patients at some point one group may be required to recruit more of one group**
PROTOCOL	
Can the protocol be shared?	**The protocol is available on the website https://www.camcovidtrials.net/trials/PROTECT**
Will study likely last longer than 6 - 9 months?	**At the moment we only have HRA approval for 9 months to dose with Niclosamide and this is because we only have data to prescribe for this long, it may be that during this trial there will be more information and we can dose for longer. It may be that with some of the other drugs we are working with we may be able to dose for longer, however 9 months should take us over the further risk period for infections**
The protocol excludes patients with nasal/sinus issues. Are vasculitis patients with ENT involvement excluded?	**No. They can go in the trial, only those with quite major structural nose damage are excluded. If they've had prior ENT treatment for their vasculitis which is well controlled they can enter the study**
If a potential participant has had routine COVID-19 swab, does the test need to be repeated after consent?	The Sponsor has confirmed that COVID-19 swab is not a trial procedure and so it is acceptable to use the result of a routine COVID-19 swab to assess the exclusion criterion. For a routine swab result to be acceptable, samples should have been obtained up to 2 days prior to screening visit.
Is there any precaution to be taken when obtaining COVID-19 swab samples for patients receiving the trial treatment?	Yes, swab samples should be obtained before or at least 2 hour after the trial treatment dose.
When is the trial recruitment phase ending?	The current end of trial recruitment phase is planned by the end of August, but this might change in the future.
When is the trial follow-up phase ending?	The current end of trial follow-up phase is planned by the end of February, but this might change depending on the event rate. All participants should receive trial treatment for a minimum of 6 months and can receive trial treatment for up to 9 months.
How long is the trial treatment administered? Once the trial ends, will participants have access to the active drug?	Trial treatment duration is event-driven with a maximum treatment period of 9 months and expected minimum of 6 months. Once the target events have been observed, if efficacy of the treatment is confirmed, there is the intention to provide access to the active drug.

CONSENT	
Is the participant consent process PI-led?	Consent must be obtained by the PI or delegated sub-investigators.
Can a patient be part of other clinical trials while enrolled to PROTECT?	Yes. Co-enrolment to other clinical trials is allowed with the only exception of other COVID-19 prophylactic trials. Once enrolled, according to protocol, a participant will stop the trial treatment if they are admitted to hospital due to COVID-19 infection to allow inclusion in COVID-19 treatment trials.
Potential participants are shielding and our site is running all clinics remotely either by phone or video. Can we use these methods for the consenting and follow up visits or do they have to be face to face?	Consent must be obtained in person at the screening visit during which samples are collected. All other follow up visits are expected to be performed remotely except for the final visit at the end of the participant involvement in the trial, when more samples will be collected.
Do you see the reduction in admission of patients having an impact on the study?	**Although this is a prophylaxis study we encourage every participant to have a vaccine as part of SOC. Participants on hemodialysis and those receiving immunosuppressive medications do not have the same protection from vaccines as the healthy population We do feel the need to have more patients than originally planned and certainly feel there is a need for this study over and above vaccination**
In addition to the exclusion of WOCBP Is there anything about male participants needing to practice true abstinence / agreeing to use barrier methods?	**No. Only women of childbearing age need to use contraception.**
How specific is the Glomerulonephritis, vasculitis group of patients in terms of eligibility for the study?	**If there is a specific patient you want to include and are unsure please discuss with CI as they want to be inclusive as possible**
CONTRACTING	
What is the closing date for the trial?	Trial is expected to recruit for 6 months and follow up participants for 6-9 months. Currently the end of recruitment period is by the end of summer. However, PROTECT is an event driven trial and recruitment target may vary in the future with recruitment period extensions.
Is the study UPHR badged	**Yes it is**
DATABASE, RECRUITMENT, AND RANDOMISATION	
If the trial is open does this mean that	**Only the first 70 haemodialysis patients require PK**

PK samples will be needed in all sites?	**sampling already reached 30 participants so anticipating in next 4-5 weeks PK sampling should be complete. Not all sites will require PK sampling. You cannot recruit hemodialysis patients until the 70 have been recruited but sites can recruit transplant or vasculitis patients before then**
Given PK sampling only on the first 70 participants, has PK sampling now concluded?	**No, 72 patients recruited so far are from all populations**
If the study goes international will it be a case of competitive recruitment?	**We are anticipating the need to increase our sample size and there may be other potential agents coming on board. Open to as many sites as possible there is no caps on recruitment encouraging as many sites and participants as possible**
EQUIPMENT	
Do we need to source our own equipment for the COVID antibody testing and PCR tests?	Antibody testing will be performed centrally. PCR test should be performed locally.
DOCUMENTATION	
Is the site supposed to monitor and report COVID infections of recruited participants during follow-up?	Positive COVID test information will be automatically collected from the PHE (or equivalent national agencies). Please, remind patients to answer “Yes” to the question "have you had a positive COVID test since last assessment" in the follow up questionnaire if they are tested positive.
Is the oversight of stock done electronically?	The randomisation system will send automatic lock stock notifications to local and central staff. IMP shipments will be ordered centrally in agreement with the local pharmacist. A low stock notification will be automatically sent from Sealed Envelope to the central staff.
Can I ask how will shipments be receipted? Are pharmacy not required to register the shipment as arrived within IxRS system?	Rena Clinicial will distribute IMP to sites after central order by the Coordinator. Site will confirm receipt to Rena Clinical copying the coordinator so that the coordinator can allocate the kits to the site in SealedEnvelope
Why is the Excess treatment cost in SoECAT higher than the PSA per-patient fee?	This is only temporary due to the short expiry date for the IMP which requires dispensation and couriering of IMP to patients more often. Once expiry date is extended dispensation will be cut to a third of the current cost. There is also a mistake in the accountability of returned IMP which should only be costed at the end of the patient

	involvement in the trial instead of every follow-up visit. With all these changes, the mean Excess treatment cost should be lower than the per-patient fee.
Where is the Participant Questionnaire v2.0 listed in the HRA approval letter?	The Participant Questionnaire v1.0 was renamed as Follow-up Symptom Checker for participants when changed to v2.0 during the submission process. Unfortunately, HRA listed it with the old name in the Approval letter. There is no Participant Questionnaire v2.0 for this study.