Chloroquine/ hydroxychloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study

UK Trial Monitoring v1.0, 6th July 2020

MORU Tropical Health Network

wellcome

UNIVERSITY OF OXFORD

UNIVERSITY OF OXFORD DIABETES TRIALS UNIT
The Oxford Centre for Diabetes, Endocrinology and Metabolism

brighton and sussex medical school

Study Monitoring

Remote monitoring visits (MV) will be conducted at all sites at pre-specified intervals, to ensure that the research team is conducting the study according to the protocol, study specific SOPs; and that the data collected are of high quality and being recorded properly.

Scheduled monitoring will occur as follows:

- Initial quality assessment (after first 5 participants)
- 3 interim MVs (following recruitment of 50, 100 and 400 participants respectively)
- Close-out visit

Triggered Visits
Following review of data provided at scheduled MVs future interim MV's may be conducted earlier than scheduled irrespective of recruitment total.

Monitoring activities will include review of the following:

- Informed Consent
- Eligibility assessment
- IMP compliance and accountability
- Adverse events / serious adverse events (AE/SAEs)

Study Monitoring (Cont.)

Monitoring activities will be conducted on behalf of the Diabetes Trials Unit by CodClinical Ltd.

As per the schedule listed previously the Monitor will contact your site and request appropriate trial documents and logs as part of the remote monitoring activities.

Documents should be provided securely via a secure server which the monitor will provide the location to when requesting documents. Please do not email documents.

All personally identifiable data should be redacted prior to sending unless otherwise stated.

Site Facilities, Equipment and Supplies

As part of NHS Trust Capacity and Capability it will be assumed there are appropriate clinic areas (where participants will be seen), laboratory, pharmacy and study office space to conduct the trial. The Monitor may request to see evidence of this remotely (e.g. via video call).

It will also be assumed appropriate equipment required for the conduct of the study (*i.e.*, computer, internet connection) is available.

Lab, clinical and Study consumable provided by the Sponsor are detailed in the Non-Commercial Agreement and a list of supplies to be provided by the site will be sent during study set-up.

Please discuss any potential issues with facilities, equipment or supplies during trial set-up with the central trial team.

Study Closure & Archiving

For sites the end of the study will be the date of the last visit of the last participant, the last dose of the study drug or up to 60 days after the diagnosis of COVID-19/ ARI of the last participant enrolled in the study, whichever comes last.

All sites will have a remote close-out visit (COV) for COPCOV. Study close-out will be conducted after the last participant in the study has completed the last follow-up visit and all data queries have been resolved.

Sites will be informed to archive their ISF for 5 years.

In the UK, participants will be followed up centrally after the completion of the trial period via medical records and organisations such as NHS digital - this will be for 15 years after the last participant is randomised in the UK.

Additional Information

Reference Documents:

- COPCOV UK Protocol

Always refer to https://www.copcov.org/sites.html for correct version of documents

If you have any further questions please contact copcov@dtu.ox.ac.uk