**1- Study design**

Open-label randomized multicountry clinical trial

Comment:

Open-label (opposite to double-blind approach ) means both the researchers and participants know which treatment is being administered.

Problem with Open label trials:

A blinded trial is regarded as being less subject to bias than an open trial because it minimizes the effect of knowledge of treatment allocation on reporting of outcomes.

**1- Data and Safety Monitoring Board**

Interim trial analyses are monitored by a Global Data and Safety Monitoring Committee, which is an independent group of experts.

Comment:

Global Data and Safety Monitoring Committee: UAE should be party of this committee

**2- Additional data**

Countries, or particular groups of hospitals, may want to collaborate in making further serial measurements or observations, relating to areas such as virology, blood gases or chemistry and lung imaging. It also possible to incorporate documentation of other aspects of disease status, for example, through linking in electronic healthcare records and routine medical databases. While well-organised additional research studies of the natural history of the disease or of the effects of the trial treatments could well be valuable, they are not core requirements.

Comment:

Will the EDC system of solidarity allow data entry and storage of these additional information?

**3- Ethics approval**

Pending, WHO Ethics Review Committee and Ethics Committees of countries implementing the protocol

Comment:

Ethics Committees of countries implementing the protocol

**4- Intention to publish date**

31/12/2021

Comment:

Too long! Almost in one year and 8 months!

**4- Treatment**

1. Local standard of care alone

OR local standard of care plus one of

2. Remdesivir (daily infusion for 10 days)

3. Chloroquine or hydroxychloroquine (two oral loading doses, then orally twice daily for 10 days)

4. Lopinavir + ritonavir (orally twice daily for 14 days)

5. Lopinavir + ritonavir ((orally twice daily for 14 days) plus interferon-beta (daily injection for 6 days)

**5- Primary outcome measure**

All-cause mortality, subdivided by the severity of disease at the time of randomization, measured using patient records throughout the study

**6- Secondary outcome measures**

Measured using patient records:  
1. Duration of hospital stay (hours)  
2. Time to first receiving ventilation (or intensive care) (hours)

ADD:

Clearance time of virus RNA