World Health Organization

“Solidarity” clinical trial for COVID-19 treatments

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Solidarity" is an international clinical trial to help find an effective treatment for COVID-19, launched by the World Health Organization and partners.

The Solidarity Trial will compare four treatment options against standard of care, to assess their relative effectiveness against COVID-19. By enrolling patients in multiple countries, the Solidarity Trial aims to rapidly discover whether any of the drugs slow disease progression or improve survival. Other drugs can be added based on emerging evidence.

Until there is sufficient evidence, WHO cautions against physicians and medical associations recommending or administering these unproven treatments to patients with COVID-19 or people self-medicating with them. WHO is concerned by reports of individuals self-medicating with chloroquine and causing themselves serious harm. WHO guidance on compassionate use can be found here.

Update on hydroxychloroquine

Originally posted 27 May 2020, updated 17 June 2020

On 17 June 2020, WHO announced that the hydroxychloroquine (HCQ) arm of the Solidarity Trial to find an effective COVID-19 treatment was being stopped.

The trial's Executive Group and principal investigators made the decision based on evidence from the Solidarity trial, UK's Recovery trial and a Cochrane review of other evidence on hydroxychloroquine.

Data from Solidarity (including the French Discovery trial data) and the recently announced results from the UK's Recovery trial both showed that hydroxychloroquine does not result in the reduction of mortality of hospitalised COVID-19 patients, when compared with standard of care.

Investigators will not randomize further patients to hydroxychloroquine in the Solidarity trial. Patients who have already started hydroxychloroquine but who have not yet finished their course in the trial may complete their course or stop at the discretion of the supervising physician.

This decision applies only to the conduct of the Solidarity trial and does not apply to the use or evaluation of hydroxychloroquine in pre or post-exposure prophylaxis in patients exposed to COVID-19.

Key Links

18 March 2020

WHO Director-General's opening remarks at the media briefing on COVID-19 - 18 March 2020

Rationale

The pressure COVID-19 puts on health systems means that WHO considered the need for speed and scale in the trial. While randomized clinical trials normally take years to design and conduct, the Solidarity Trial will reduce the time taken by 80%.

Enrolling patients in one single randomized trial will help facilitate the rapid worldwide comparison of unproven treatments. This will overcome the risk of multiple small trials not generating the strong evidence needed to determine the relative effectiveness of potential treatments.

Participation in Solidarity

As of 3 June 2020, more than 3500 patients have been recruited in 35 countries, with over 400

hospitals actively recruiting patients. Overall, over 100 countries have joined or expressed an interest in joining the trial, and WHO is actively supporting 60 of them with:

- **ethical and regulatory approvals of the WHO core protocol;**
- **identification of hospitals participating in the trial;**
- **training of hospital clinicians on the web-based randomization and data system;**
- **shipping the trial drugs as requested by each participating country.**

The greater the number of participating countries, the faster results will be generated. WHO is facilitating access to thousands of treatment courses for the trial through donations from a number of manufacturers. WHO is also inviting developers and companies to collaborate on ensuring affordability and availability of the treatment options if they prove effective.

Treatment options under study

The treatment options are: Remdesivir; Lopinavir/Ritonavir; and Lopinavir/Ritonavir with Interferon beta-1a. The treatment options were originally selected based on evidence from laboratory, animal and clinical studies.

Remdesivir was previously tested as an Ebola treatment. It has generated promising results in animal studies for Middle East Respiratory Syndrome (MERS-CoV) and severe acute respiratory syndrome (SARS), which are also caused by coronaviruses, suggesting it may have some effect in patients with COVID-19.

Lopinavir/Ritonavir is a licensed treatment for HIV. Evidence for COVID-19, MERS and SARS is yet to show it can improve clinical outcomes or prevent infection. This trial aims to identify and confirm any benefit for COVID-19 patients. While there are indications from laboratory experiments that this combination may be effective against COVID-19, studies done so far in COVID-19 patients have been inconclusive.

Interferon beta-1a is used to treat multiple sclerosis.

18 June 2020: On 17 June 2020, WHO announced that the hydroxychloroquine (HCQ) arm of the

Solidarity Trial to find an effective COVID-19 treatment was being stopped, so hydroxychloroquine was removed from this page as a listed treatment option under study.

25 May 2020 Update: As per the initial trial protocol, chloroquine and hydroxychloroquine had both been selected as potential drugs to be tested within the Solidarity Trial. However the trial was only ever pursued with hydroxychloroquine, so chloroquine was removed from this page as a listed treatment option under study.

Support for Solidarity

“The quest for knowledge about the coronavirus is a global effort. The Solidarity Trial is an important part of the puzzle. I am proud that Norway will contribute both by having the first patient included in the study. I would like to commend the WHO for the global leadership and its initiative in setting up the Solidarity Trial.”

- Bent Høie, Minister of Health and Care Services, Norway

“There is only one way the world can exit this pandemic – and that is through science. We need diagnostics to detect and limit the spread of this virus, vaccines to provide long-term protection, treatments to save lives in the shorter-term and social science to understand the behavioural and societal implications. It’s critical that the global research effort is rapid, robust and is conducted at scale and co-ordinated across multiple countries. The World Health Organization’s Solidarity Trial will provide this by testing existing and new drugs to treat COVID-19 and ensure equitable access to any drugs that prove effective. The start of these clinical trials is hugely important and an incredible achievement. Global powers must now step-up to ensure the WHO has all the support needed.”

- Dr Jeremy Farrar, Director of Wellcome and Chair of the WHO R&D Blueprint Scientific Advisory Group

How the Solidarity Trial works

Adults with COVID-19 admitted to participant hospitals can join this study. Eligible patients will be asked to sign to show they understand the possible risks and benefits and consent to joining the study. The medical team responsible for each patient will check whether any of the study treatments would definitely be unsuitable.

After those checks, brief identifying details and any other conditions are digitally recorded for the patient, who is then randomly allocated to one of the study options. This may or may not involve one of the study treatments. Neither the patient nor the medical staff choose which of the study options a patient will receive, as a computer makes this allocation at random.

Critical anonymized information for the trial will only be collected at the randomization stage and when the patient is discharged or dies: which study drugs were given (and for how many days); whether ventilation or intensive care was received (and, if so, when it began), date of discharge, or date and cause of death while still in hospital.

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

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.

Adults (age ≥18 years) recently hospitalised, or already in hospital, with confirmed COVID-19 and, in the view of the responsible doctor, no contra-indication to any of the study treatments will be randomly allocated between

- Local standard of care,

OR local standard of care plus one of

- Remdesivir
- Lopinavir with Ritonavir
- Lopinavir with Ritonavir plus Interferon beta-1a.

Underlying conditions recorded are: diabetes, heart disease, chronic lung disease, chronic liver

disease and asthma, extending to HIV and tuberculosis in the African region.

Severity of illness at entry is determined by recording: shortness of breath, being given oxygen, already on a ventilator, and, if lungs imaged, major bilateral abnormality.