CRASH-19

TRIAL OVERVIEW

The CRASH-19 trial is a multinational, open-label, factorial, randomised trial evaluating the effects of aspirin, losartan and simvastatin in adults hospitalised with suspected or confirmed acute COVID-19 infection. Ten thousand patients will be randomly allocated to one of eight treatment arms. Trial treatments are given in addition to usual standard of care at the trial hospital.

ASSESS ELIGIBILITY

Eligible if:

- Admitted to hospital with confirmed or suspected* acute COVID-19 infection
- Adult ≥ 40 years old
- No indication or contraindication to aspirin, losartan and simvastatin
- Not pregnant
- Not on mechanical ventilation
- Not terminally ill / approaching end of life

NB: Patients hospitalised without symptoms of acute COVID-19 infection should not be recruited even if they test positive for COVID-19.

*** We use the following WHO criteria for a suspected case:**

A. *Patient with acute respiratory illness* AND a history of travel to or residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset; OR*

B. *A patient with any acute respiratory illness AND having been in contact with a confirmed or probable COVID-19 case in the last 14 days prior to symptom onset; OR*

C. *A patient with severe acute respiratory illness* AND requiring hospitalisation AND in the absence of an alternative diagnosis that fully explains the clinical presentation.*

** fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath*

COMPLETE INFORMED CONSENT PROCESS

Depending on patient's capacity: Written informed consent, personal representative consent or professional representative consent.

COLLECT BASELINE DATA

Complete online Entry Form data via online database to confirm eligibility and collect baseline data.

RANDOMISE AND OBTAIN TREATMENT ALLOCATION

The trial database will generate a randomisation number and assign the treatment allocation which will appear on screen and will be emailed to the person randomising.
RECORD randomisation number in the patient's medical records.

PRESCRIBE AND ADMINISTER TRIAL TREATMENT(S)

Prescribe and give the allocated treatment(s) immediately after randomisation.
Give allocated treatment(s) once daily until discharge or Day 28 whichever is sooner. See protocol for treatment modifications

COLLECT OUTCOME DATA

Complete the online outcome form at death, hospital discharge, or 28 days after randomisation, whichever occurs first.

Report any Serious Adverse Reactions up to 28 days after randomisation as per protocol.