Supplementary material *BMJ Open*

Supplement 2. The World Health Organization Trial Registration Data Set for the COPEP trial

1. Primary Registry and Trial Identifying Number
Swiss National Clinical Trial Portal (SNCTP 000003732)

2. Date of Registration in Primary Registry
17.04.2020

3. Secondary Identifying Numbers
Clinicaltrials.gov (NCT04364022);

4. Source of Monetary or Material Support
Fondation privée des HUG

5. Primary Sponsor
Fondation privée des HUG

6. Secondary Sponsor(s)
SNF grant submitted

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9. Public Title
Médecin adjointe agregée
Director of the HIV Unite

10. Scientific Title
Chef de Clinique Scientifique
Epidemiologist

11. Countries of Recruitement
Switzerland

12. Health Conditions(s) or Problem(s) Studied
COVID-19

13. Intervention(s)

Participants will be randomized in household clusters, 2:1 to receive either LPV/r, 400mg/100mg (2x 200mg/50mg pills) twice daily for 5 days; or surveillance. The first dose of LPV/r will be taken during the baseline visit, as directly observed therapy.

14. Key Inclusion and Exclusion Citeria

Inclusion Criteria

1. Documented close contact with a PCR-confirmed SARS-CoV-2 positive individual;
2. ≥ 16 years of age;
3. Informed consent documented by signature (including parent's or legal guardian's signature if the participant is 16 and 18 y.o.);

Exclusion Criteria

1. Fever (temperature >38.0°) and/or respiratory symptoms (cough, dyspnoea) and/or new anosmia/ageusia;
2. Individuals with previous confirmed SARS-CoV-2 infection within the last six months;
3. Known impairment of liver function;
4. Known hypersensitivity to any of the study medications;
5. Use of any medications that are contraindicated with LPV/r using the website www.hiv-druginteractions.org/checker
6. Individuals on boosted protease inhibitor as part of an antiretroviral therapy
7. Inability to be followed-up for the trial period

15. Study type:

Study type: interventional
Method of allocation: randomized
Masking: open

16. Date of First Enrollment

23/04/20

17. Sample Size

300

18. Recuitement Status

Recruiting

19. Primary outcomes:

Outcome: incidence of COVID-19
Measurement: ≥ 1 symptom compatible with COVID-19 and either
i) a positive PCR for SARS-CoV-2 in oropharyngeal swab and/or
ii) a seroconversion of IgG only or IgG and IgA for SARS-CoV-2 at day 21 in individuals with negative serology at baseline. In case of seroconversion of IgA only, seroconversion of IgG using more sensitive spike-based recombination immunofluorescence assay (S-rIFA) will be assessed.
Timepoint: 21 days

20. Key Secondary Outcomes

Outcome: incidence of COVID-19
Measurement: modified ITT (negative SARS-CoV-2 PCR and serology at baseline)
Timepoint: 21 days

Outcome: incidence of SARS-CoV-2
Measurement: i) a positive PCR for SARS-CoV-2 (oropharyngeal swab) amongst those with a negative PCR at baseline and/or
ii) a seroconversion of IgG only or IgG and IgA for SARS-CoV-2 at day 21 in individuals with negative serology at baseline. In case of seroconversion of IgA only, seroconversion of IgG using more sensitive S-rIFA will be used.
Timepoint: 21 days

Outcome: severity of COVID-19
Measurement: 7-point ordinal scale
Timepoint: 14 days post onset of disease, end of hospitalization where applicable

21. Ethics review

The study has been approved by the following boards: Commission cantonale d'éthique de la recherche, Geneva, Switzerland (2020-00864), Ethikkommission Nordwest- und Zentralschweiz, Comitato Etico Cantonale Swissmedic (Swiss Agency for Therapeutic Products).
All participants will be asked for written informed consent. This trial will be conducted in accordance to Good Clinical Practice and the Helsinki Declaration.

22. Completion data

N/A

23. Summary Results:

N/A

24. IPD sharing statement:

Plan to share IPD: the IPD for this trial will not be made available
Plan description: study protocol