Universität Basel

Research Project

Immediate and pre-emptive therapies for SARS CoV-2 positive and negative patients with high risk for Covid-19 pneumonia: Immunocompromised Collaborative Host Swiss Cohorts Based Trial Platform Initiative

Third-party funded project

Project title Immediate and pre-emptive therapies for SARS CoV-2 positive and negative patients with high risk for Covid-19 pneumonia: Immunocompromised Collaborative Host Swiss Cohorts Based Trial Platform Initiative
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Project start 01.07.2020
Probable end 30.06.2022
Status Completed

Endorsed public health measures have confined the SARS-CoV-2 pandemic in Western Europe but leave due to very low herd immunity a high proportion of the population at risk of infection. In a not unlikely second epidemic routine and repetitive PCR testing is essential for at risk populations for complicated SARS-CoV-2 for infection protection and monitoring. It is less clear, whether preventive treatment in individuals with Covid-19 infection with mild symptoms or in those uninfected but at high risk of complicated SARS-CoV-2 infection may offer additional protection against complicated SARS-CoV-2 infection. Methods We will set up a trial platform which will be implemented and nested into the Swiss HIV Cohort Study and the Swiss Transplant Cohort Study to investigate during a new epidemic the comparative effectiveness of immediate and preventive therapy with emerging antivirals against SARS-CoV-2. Patients in these cohorts with mild SARS-CoV-2 infection with no pneumonia and SARS-CoV-2 negative patients at risk for complicated infection due to age, HIV (<350-500 CD4 cells/ţl), solid organ transplantation or with risk factors for COVID-19 pneumonia who consent to participate in the trial will be randomised to candidate antivirals. The primary composite endpoint is CT-confirmed pneumonia, hospitalization or death from any cause. Need for immediate hospitalization for any reason is an exclusion criteria. Based on accumulating evidence of ongoing and published trials of antiviral drugs against SARS-CoV-2 infection, patients will be randomized in the presence of one active drug to drug A versus control, in the presence of two drugs to drug A or B or control. Interim analyses are planned to adaptively randomize patients to the most effective comparator arm (intervention duration 18 months). Arms may be suspended for ineffectiveness and new arms may be added to the trial as novel therapies emerge. Interventional drugs will be selected by expert panels from both cohorts with provision of external up-to date evidence from meta-analytical reports. Relevance The project intends to establish a trial platform that is nested into existing cohort infrastructure to investigate the comparative effectiveness of early and preemptive upcoming antiviral therapies to prevent complications from SARS-CoV-2 in two very vulnerable patient populations. The chosen innovative trial designs allows for rapid trial implementation in case of a second epidemic and in the absence of an effective vaccine. The trial platform can be easily extended to involve further Swiss (or international) cohorts and will serve as an ideal instrument for potential future pandemics.

Financed by
Swiss National Science Foundation (SNSF)

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