CONTROL OF COVID-19 OUTBREAKS IN LONG TERM CARE

Control of COVID-19 outbreaks in long term care (CONTROL-COVID-Favipiravir): Protocol Summary

Background:

A novel coronavirus, SARS-CoV-2 emerged in December 2019. Causing a febrile respiratory illness known as COVID-19, this virus has rapidly spread around the globe. Early in the pandemic, it became apparent that the elderly are disproportionately bearing the burden of this disease, with the majority of deaths occurring in those older than 60 years of age. Outbreaks have begun in long-term care homes (LTCHs), followed by high numbers of deaths. Interventions are urgently needed to control these outbreaks in LTCHs in order to minimize the harms of the pandemic on our elderly patients.

Chemoprophylaxis (giving medication to prevent infection) has been a cornerstone in the management of LTCH outbreaks of influenza. Finding a similar strategy for outbreaks of COVID-19 has been identified as a research priority by the World Health Organization (WHO). While there are no confirmed therapies for COVID-19 yet, there is laboratory evidence suggesting that existing medications may be effective for treatment or prevention. Favipiravir, a broad-spectrum anti-viral agent, exhibits activity against SARS-CoV-2 and has demonstrated benefit in early COVID-19 studies. Favipiravir is an ideal candidate for preventative therapy, as it is available for oral administration and has a favorable safety profile.

Proposed Trial:

We thus propose a cluster-randomized placebo-controlled trial of preventative therapy with favipiravir for the control of COVID-19 outbreaks in LTCHs for the elderly.

Recruitment Process:

Study information will be first provided to LTCH administration, medical directors, and resident's councils, and should they agree that participation in the study is a reasonable option for their residents and staff, then information will be provided to residents and staff. LTCHs will be asked to report outbreaks to the study. An outbreak will be defined as ≥ 2 symptomatic residents with confirmed COVID-19 identified within 7 days on one unit.

Upon identification of an outbreak, study staff will contact residents and staff of the unit to discuss the study, assess for contraindications to enrollment, and obtain informed consent to receive study drug, and to be followed for clinical outcomes, adherence, and safety.

Intervention:

Favipiravir or placebo will be offered to all consenting residents and staff who will be working on the unit during the chemoprophylaxis period, according to the randomized allocation. Study drug will continue for 25 days. For residents diagnosed with COVID-19 at the beginning of the study, a treatment dosage of favipiravir (or placebo) will be provided for 14 days.

Follow-up:

Surveillance for infection will occur as usual for resident illness within each facility; staff will be asked to report symptoms and will be screened for symptoms each time they enter the building. Consenting residents and staff will be swabbed at day 0, day 14 and day 40 to identify asymptomatic infections. Study staff will conduct interviews and/or chart reviews for consenting participants on day 0, day 14, and day 40, with additional follow-up at day 60 for residents. The primary outcome will be control of the outbreak, defined as no new microbiologically confirmed cases of COVID-19 for 24 consecutive days up to day 40 after the study drug was started.