

Control Group

Information sheet for Barwon Health staff

BH Reference Number 22/124: Barwon Health Staff Access to Molnupiravir

BACKGROUND

- Molnupiravir (Lagevrio®) is an oral antiviral therapy that is currently provisionally approved by the Therapeutic Goods Administration (TGA) for the treatment of symptomatic COVID-19 in people who have risk factors for severe disease.
- Molnupiravir reduces the risk of hospitalisation or death due to COVID-19 by 30% in this patient demographic.
- Additionally, the use of Molnupiravir may reduce the severity and duration of your symptoms, as well as reduce your infectiousness meaning that you are less likely to transmit the virus to your household members.
- It is well tolerated, with few side effects, and easily prescribed due to no drug-drug interactions or dosing issues with those who have organ dysfunction.

BARWON HEALTH STAFF ACCESS TO MOLNUPIRAVIR

- Given the enormous impact that this COVID-19 Pandemic has had on the healthcare system, Barwon Health is currently looking into various ways in which we can help support our staff.
- We believe that Molnupiravir is likely to bring benefit to everyone, even those who do not have risk factors for severe disease; namely by reducing the length and severity of illness and reducing the spread of the virus within a household. We also feel it may allow staff to feel more secure at work knowing they have access to treatment if they become infected.
- It is important to understand that the use of Molnupiravir in this setting is "off-label" meaning that it is not currently approved by the TGA for those not at risk of severe disease.
- Furthermore, being a new medication, it is unknown whether there are any long-term adverse effects of the treatment
- When determining whether there is any benefit to receiving a medication, it is important to compare the effects of the medication on a person who takes it to a person who did not receive the medication (i.e. a control group).

HOW TO PARTICPATE

- You are receiving this handout as you are a member of University Hospital Geelong Staff, and have registered your COVID-19 positive status with your manager.
- If you have not requested access to Molnupiravir, we invite you to complete our participant survey as a member of the control group (the group that is not receiving treatment).
- Please note, that the fact that you do not wish to receive Molnupiravir, will not impact your current or future care at StaffCare.

- You will receive three surveys at different time points; two weeks, three months and six months post COVID-19 illness. Each survey should not take longer than five minutes to complete
- The researchers will be able to see whether you have responded to your survey, as an individualised link is sent to each participant
- If you do not complete the first survey (two weeks post COVID-19 illness), you will receive a reminder email one week after the original invite. If you still do not complete the survey, you will not receive the subsequent surveys, and your email address will be removed from the mailing list
- All survey responses are entered into a computer database where they are securely stored. The responses are stored in a de-identified manner, meaning that your sensitive health information cannot be linked back to you in any way.
- Participation in this research is voluntary, and you are under no obligation to complete the survey

DATA MANAGEMENT

- Your email address will be stored in a password protected RedCap database
- The researchers will be able to see whether you have completed your survey, and if you have not completed the survey within one week of receiving it, your email address will be removed from the database, and you will not receive any further surveys
- Please note however, that when your survey is returned, it is delivered to a RedCap database in a de-identified manner, meaning the researchers cannot identify which set of responses are yours

QUESTIONS AND CONTACTS

Should you have any questions or concerns, please contact

StaffCare Reception 4215 3220

Principal Investigator: Jessica O'Keeffe via switchboard 4215 0000

DETAILS OF RESEARCH TEAM

Principal Investigator: Jessica O'Keeffe

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Co-investigators: A/Prof Daniel O'Brien, Dr Arvind Yerramilli, Ms Janice Chaing, Dr Greg Weeks, Dr Ross Nolan, Dr Jeff Urquhart, Dr Margaret Somerville

ETHICS APPROVAL AND COMPLAINTS

This study has been approved by the HREC of Barwon Health.

If you have any questions, please contact the Principal investigator using the above details.

If you have any complaints about the conduct of the research, please contact the Manager of the Barwon Health Research Ethics, Governance & Integrity (REGI) Unit on 4215 3372.

Thank you for your interest in this study.