GETAFIX - **G**lasgow **E**arly **T**reatment **A**rm **F**av**I**piravir$^{\chi}$: A randomised controlled study of favipiravir as an early treatment arm in COVID-19 patients

Summary Information for <u>Inpatients</u>

NHS Greater Glasgow and Clyde and the University of Glasgow are running a trial to test the effects of an antiviral drug, favipiravir, in patients who have tested positive for COVID-19. The following is a brief summary of the study – if you are interested in taking part and would like to know more, please let your doctor or nurse know and they will give you more detailed information to allow you to make a decision.

What is the study about?

The purpose of the study is to see if giving patients who have milder symptoms of COVID-19 (not requiring oxygen support) a drug called favipiravir will help with their symptoms and reduce the time it takes to recover. We are targeting patients who are at higher risk of going on to develop more severe COVID-19. Around 300 patients will take part in the study, and half will be given the drug along with the normal standard treatment, and the other half will receive normal standard treatment alone. We can then compare the two groups to see if the drug has a positive effect and if it may be useful in treating future patients with COVID-19.

What is the drug being tested?

Favipiravir is an antiviral drug that has been shown to have activity against the influenza virus, and has been approved for this purpose in Japan. It is thought that the drug stops the virus from multiplying inside the body, and we want to test if it can do the same with the COVID-19 virus. It is taken orally (by mouth) in the form of tablets for 10 days.

What would I need to do?

If you are interested in taking part, and have a positive COVID-19 test, you will be given more details about the trial and the opportunity to discuss with the doctors, nurses, and also family members. We will then ask you to sign a consent form, and you will have some tests to check you are suitable for the study. These include checking your pulse, temperature, breathing rate, oxygen levels, height and weight, and also taking a blood sample.

If these tests show that you can participate in the study, you would then be randomly assigned to one of two treatment groups – **standard care** (the same care you would receive if you were not on a trial) or **standard care + favipiravir**. You will be told which group you have been assigned to.

Daily information about how you are feeling, medications being taken and vital signs (such as blood pressure and temperature) will be recorded.
All patients on the trial will have some additional blood tests and nose and throat swabs which will be sent to labs for research purposes. Full details of these are given in the Patient Information Sheet.

Patients in the group who are to be given favipiravir will take 9 tablets on the first day, followed by another 9 tablets 12 hours later. On days 2-10, patients will take up to 4 tablets, followed by up to another 4 tablets 12 hours later. The tablets are of medium size (just under 9mm in diameter) so most people will be able to swallow them without too much difficulty.

Patients in the group receiving favipiravir treatment who are discharged from hospital before the end of the course will be given the rest of the tablets to take at home.

All patients will be asked to come to a clinic for three follow-up visits - at two weeks, one month and two months after starting the trial. The tests you had at screening, including blood tests and nose and throat swabs will be repeated at these visits, and you will also be asked to complete a questionnaire. If you were unable to come to these visits for any reason, one of the clinical team would call you instead.

Am I likely to benefit from this?
It is possible that favipiravir may help to reduce the symptoms of COVID-19 or reduce the time taken to recover. However, even if you do not benefit directly, the information from this study will help improve our understanding of using favipiravir to treat COVID-19 for future patients.

Are there any side effects from favipiravir?
As well as possible benefits, the trial medicine can also produce side effects although not everyone will get them. Potential side effects of the treatment being used in the trial, and the percentage of people who experienced them, are summarised in the Patient Information Sheet.
Patients taking favipiravir will be monitored by the study team whilst in hospital and contacted daily while taking the drug if discharged. If at any time you or your doctor felt the side effects were a problem for you, the drug would be stopped.

Will my taking part in the trial be kept confidential?

You can be assured that any data collected during the course of this trial and any of the results published will not identify you personally.

What if I don't want to take part?

There is absolutely no obligation to take part – if you would rather not be in the trial, just let your doctor or nurse know. Your treatment will continue as normal and will not be affected in any way.

Also, if you decide you do want to take part and then change your mind, you can withdraw from the study at any time. Again, this will not affect your future treatment.

Will I be paid for taking part?

You will not receive any payment for taking part in the study, but we will cover reasonable travel expenses for patients who are able to attend follow up visits.

Please note that favipiravir can cause harm to an unborn child. If you are pregnant or breastfeeding you will not be eligible to take part in the study, and you should not become pregnant or father a child within 3 months of taking the study drug.