



Radcliffe Observatory Quarter, Woodstock Road, Oxford. OX2 6GG
Tel: 0800 138 0880 • principle@phc.ox.ac.uk • www.principletrial.org

Date:

Dear Dr _____,

Name of patient:

Patient's date of birth:

This patient was entered into the PRINCIPLE trial on (insert date): _____

Further information about PRINCIPLE is available on the attached sheet or at
www.principletrial.org

A copy of your patients consent form is attached. **Please retain the consent form, along with this letter, in your patient's medical record.** Please note that your patient has given consent for us to gather information from their medical notes.

The treatment your patient has been randomised to receive is:

Trial Treatment: _____
at [dose] for [duration]

For patients in the active treatment arm, please put the drug details as an 'outside' prescription in your clinical record so that it is visible in the Emergency Care Summary if the patient contacts NHS24 or is admitted to hospital.

Please report any Serious Adverse Events (SAEs) other than hospitalisation or death due to COVID-19 infection to the Scottish trial team within 24 hours.

[Any relevant other local information including local arrangements re swabs]

PRINCIPLE Trial details

Site ID:

Local trial team contact details:

PRINCIPLE Patient ID:

Many thanks.

The PRINCIPLE team

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Platform Randomised trial of Interventions against COVID-19 In older peoPLE

GP Letter Scotland, **Version/Date: v2.0 11 September 2020, EudraCT number:2020-001209-22**

Professor Christopher Butler IRAS Project number: 281958 REC Reference number: 20/SC/058

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What is the PRINCIPLE trial?

The PRINCIPLE trial is one of three UK-wide COVID-19 trial platforms (the other two are in hospitals). It will evaluate a series of drugs which are potential treatments for COVID-19. More detailed information on which drugs are currently being evaluated can be found at www.principletrial.org

What do I have to do?

The Oxford and local trial teams will manage trial medication prescribing and dispensing and core data collection. You may be asked to help with follow-up data extraction (these will be done by the trial team for most patients, but it is important that we get complete data on death and hospital admission for patients who are lost to follow-up). We would also like you to report any serious adverse events which come to your attention to the Scottish Trial contact listed on the patient notification'.

What are Serious Adverse Events (SAEs) and how do I report them?

A serious adverse event is any untoward medical occurrence that:

- results in death
- is life-threatening at the time of the event
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. Hospitalisation and death due to COVID-19 are our trial primary outcomes so do not need reporting as SAEs. Please report SAEs to the **Scottish Trial contact listed on the patient notification**. The Trial Team will need to know the PRINCIPLE Patient ID, and a brief description of when the SAE happened and what it consisted of. The trial team is responsible for assessing if the adverse event is likely related or not to the trial medication, and for reporting to regulators.

Please report SAEs using the SAE form provided, which contains date of birth, but no other personal identifiable information.

Can I refer patients to the trial?

Yes. If you see a patient who you think is likely to have COVID-19, then you can tell them to get in touch with the Oxford trial team to find out more. They can do this by any of:

Website: www.principletrial.org
Tel: 0800 138 0880
email: principle@phc.ox.ac.uk

[Please include current per protocol eligibility criteria here]

1. Be aged 50-64 years and also

The Oxford trial team will then fully screen them for eligibility.