Prophylactic Therapy in Care Homes Trial (PROTECT-CH)

Participant Information Sheet

Final v1.0, 18-May-2021

IRAS Project ID: 294832

1. You are invited to take part in our research trial

- Thank you for your interest in the PROTECT-CH trial.
- This information sheet is to help you understand why the trial is being carried out and what will happen if you decide to take part.
- We want to find out and test if there are any medications that can help prevent or reduce the spread and impact of COVID-19 in care homes.
- Please take time to read this information and ask if anything is not clear.
- It is entirely up to you whether to take part.

2. Why are we doing this trial?

Since the start of the pandemic, the lives of care home residents and their relatives have been greatly affected by COVID-19. Efforts to reduce spread of the coronavirus into care homes, such as limiting family visits, have had a significant impact on the health and wellbeing of residents. Therefore, we need to find medications to minimise this impact. Government health ministers have asked us to set up this trial to find out how we can protect care home residents from COVID-19. We will try out different medications to see which ones may help, so that residents can stay well and resume a more normal life.

3. What is the purpose of the trial?

The aim of the trial is to see if we can find medications to prevent or reduce the spread and impact of COVID-19 in care homes.

4. Why should I take part in this trial if I have had the COVID-19 vaccine?

As no vaccine is completely effective, some people may still get COVID-19. We still don't know whether being vaccinated will stop you from catching and passing on the coronavirus. So, it's important we continue to look for more preventative medications.

5. Why have I been invited to take part?

You have been invited to take part because you live in a UK care home which is taking part in this trial.

6. Do I have to take part?

It is entirely up to you whether to take part. A member of the research team will be able to answer any questions you may have. If you choose not to take part, your care will continue in the normal way.

If you decide to take part, but then change your mind at any time, you are free to withdraw without giving a reason.

7. What are the possible benefits of taking part?

We do not know which medications could prevent or reduce the spread of COVID-19. Taking part in the trial may or may not directly benefit you, but the information we collect could help future residents and older people in general.

8. What are the possible disadvantages and risks of taking part?

As with all medications, there is a small risk of side effects which we will discuss with you. We will also use the information we collect from your GP and talking with your care home staff to decide whether a particular trial medication would be suitable for you to have.

9. What would taking part involve?

To understand which medications might work we need to compare these to usual care. Government health advisors will tell us which medications they want us to test.
Your care home will be allocated a particular trial medication. If you agree to take part, you will either have your usual care plus a trial medication for 6 weeks, or carry on with your usual care alone. We won't know the allocation until all the residents in the care home have been asked if they would like to take part. Neither you, nor your care home, can choose what you will receive. This will be decided by a computer.

If you agree to take part:

1. You will be asked to sign a Consent Form to be part of the trial.
2. With your permission, we will inform your GP about your participation in this trial. We would also like to access your medical records, including those held by your GP. We would like information about your medical history and the medications you are taking. This will help us understand which of the trial medications you can have.
3. Care home staff will complete 2 questionnaires with details about your health. you will also be asked to complete these for yourself. Care home staff can help you do this.

4. You will be allocated to receive either:
   - usual care plus a trial medication OR
   - usual care alone

   Further details on the trial medications are in section 25.
5. The researchers will collect some information from your care home about your use of the trial medication and whether this has made a difference to your health. We will also collect some information from national databases and trusted third parties about your general health.
6. A small group of people will also be asked to participate in an interview with a

researcher to talk about their experiences of the trial but this is optional.

10.If I get usual care what does this mean?

If your care home is allocated to deliver usual care alone this means that you will get the care which you would normally be given for any conditions or symptoms you may have. Your usual care will be decided by your care home staff and/or doctor as normal.

11.If I get a trial medication what does this mean?

As well as your usual care you will also be asked to take one of the trial medications. You can take this trial medication at your care home. It will be prescribed and delivered to your care home free of charge. We will train and support your care home staff to give the trial medications as part of day-to-day care.

12.If I am allocated a trial medication can I stop taking it?

You are free to stop taking the trial medication at any time, without giving any reason, and without your legal rights being affected. Please speak to your care home team if you would like to stop.

If you stop taking the trial medication, the information collected will not be erased and may still be used in the trial.

13.What if I want to take part in the trial but cannot take the trial medication?

You can still take part in the trial. Your care will continue as normal and we would like to continue to collect information about your health.

14.Could there be other trial medications to test?

Yes, we could be asked to test other medications in the PROTECT-CH trial in the future. Only one trial medication will be given at a time in your care home. You will be given information on any new trial medications and we will ask if you would be happy to remain involved. There will be a period of time in between taking any trial medications.

15.Can I carry on in the trial if I become unable to make decisions for myself?

Being able to make an informed decision is often referred to as having 'capacity' to make decisions for oneself. Sometimes people who live in care homes lose the ability to make decisions for themselves through illness.

If you decide to take part in the trial, you will be asked to consent to your care home appointing a legal representative who can make decisions for you should you lose the capacity to do so.

16.What if there is a problem?

If you have a concern about this trial, please speak to the care home staff who will do their best to answer your questions. If this does not deal with your concern please contact protect-trial@nottingham.ac.uk or phone 0115 748 7710.

Insurance and indemnity for NHS trial staff is covered by the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96) 48, (England and Wales), the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) (Scotland) or the clinical negligence scheme for GPs (CNSGP). In addition, Care Homes will ensure they have appropriate insurance in place to facilitate the

conduct of the trial. There are no special compensation arrangements, but residents who take part in the trial may have recourse to the NHS complaints procedure.

17.What will happen if I don't want to carry on with the trial?

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, the information collected will not be erased and this information may still be used in the trial.

If you choose to stop taking part in the trial or are not eligible to take the allocated trial medication, we would like to continue collecting information about your health from central health service records. If you do not want this to happen, tell us and we will stop.

18. How will information about me be used?

We will follow ethical and legal practice and all your personal information will be handled in confidence. We will gather information from your medical records, your GP, your care home, trusted third parties and national databases. This will be used to do the research and to make sure it's being done properly.

You will be given a unique number to replace your personal details. However, sometimes we need to be able to link the research data with your medical records, for example using your name/date of birth/NHS number. We will need this information:

- to follow up your medical records as part of the research.
- to ask Government services such as NHS Digital, the Office for National Statistics, among others to share your medical information which is relevant to the trial.

By signing the Consent Form you are agreeing to the above.

19.How will information about me be stored and shared?

All information about you will be kept strictly confidential and will be stored safely and securely. The data collected for the trial will be collated and stored by authorised persons from the University of Nottingham and trusted third parties who are organising the research and looked at by authorised members of the research team. They may also be looked at by authorised people from regulatory organisations to check that the trial is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

When the trial has finished, some of the data will be kept so the results can be checked and your care home can be told the results. We may also carry out further analyses using your data to answer other research questions. We will ensure reports are written in such a way that no-one else could work out that you took part in the trial.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in health and social care in other Universities and organisations. Sharing research data is important to allow peer scrutiny, avoid duplication of research and to understand the bigger picture. This is usually anonymised so you could not be identified. If we need to share identifiable information, we will seek your consent. You will be made aware if the data is to be

shared with countries whose data protection laws differ from those of the UK and how we will protect your confidentiality.

20.What are my choices about how my information is used?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. After 7 years your data collected during the trial will be disposed of securely.

21.Where can I find about more about how my information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- at https://www.nottingham.ac.uk/utilities/privacy.aspx
- by sending an email to protect-trial@nottingham.ac.uk
- by calling the PROTECT-CH team at the Nottingham Clinical Trials Unit on 0115 748 7710

22.Who is organising and funding this trial? How has it been approved?

The trial is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). It is being led by Professor Philip Bath. The trial is funded through the National Institute for Health Research (NIHR) Health Technology Programme (NIHR 133443).

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by South Central – Oxford A Research Ethics Committee.

Lay members of the public are involved in the teams that oversee the running of the trial and have helped develop this information sheet.

23.What if relevant new information becomes available?

During the trial we may get new information about medications for COVID-19. If this happens your care home will tell you about this new information and discuss whether you should continue in the trial. If you decide not to carry on, your care home will make arrangements for your care to continue as usual. If you decide to continue in the trial, you may be asked to sign a new Consent Form.

24.What happens at the end of the trial?

We will inform your care home of the trial findings which can then be shared with you. The results of the trial will be presented at conferences and published as reports in scientific journals. You will not be identified in any publication.

25.What are the trial medications?

The two trial medications that government health advisors have asked us to test are:

	Ciclesonide	**Niclosamide**
Why might this trial medication be useful to prevent spread of COVID-19?	Ciclesonide reduces the ability for the coronavirus to produce new virus particles. It also reduces inflammation in the nose and lungs.	Niclosamide reduces the ability for the coronavirus to produce new virus particles. It also reduces inflammation in the nose.
How is the trial medication normally used?	Ciclesonide is currently approved to be used in the UK to treat asthma. For this trial, an unapproved version of the trial medication will be used. This is because it is made by a different company. It will be exactly the same as the approved version.	Niclosamide is used in many countries to treat tapeworm. It is normally taken as tablets that you swallow. It has been shown to be a safe medication that has been used orally worldwide for more than 40 years. A nasal spray has now been developed for prevention of COVID-19 in patients at particularly high risk of infection, but this formulation is not currently licensed for use.
How do I take the trial medication?	Ciclesonide is a drug breathed in through the mouth and nose. It will be taken once a day using an inhaler and face mask, if needed. The care home staff will help you to use this. Each use takes less than a minute.	Niclosamide is a liquid drug sprayed up the nose using a nasal pump spray with a fixed dose. It will be taken twice a day. Each use takes less than a minute.
How long do I need to take the trial medication?	You will be asked to take this medication for 6 weeks.	You will be asked to take this medication for 6 weeks.

How safe is the trial medication?	At the doses we will be using there may be occasional side effects, and these are discussed below. Some are more common than others. **Uncommon:** Nausea, vomiting, a bad taste, skin reactions or dryness at site of the inhaler or mask, oral fungal infections, headache, abnormal voice (dysphonia), cough after inhalation, tightening of the airways (paradoxical bronchospasm), eczema and rash. **Rare or very rare**: Palpitations, abdominal pain, indigestion (dyspepsia), swelling under the skin (angioedema), more likely to have an allergic response to a medication (hypersensitivity), high blood pressure (hypertension) **Unknown frequency:** Unexpected movement (psychomotor hyperactivity), sleep disorders, anxiety, depression, aggression, behavioural changes	As Niclosamide is normally taken as tablets to swallow, we do not know what the side effects of the nasal spray will be. Based on the information that we have about the safety of the medication from the oral tablet formulation there may be occasional side effects, and these are discussed below. It is however expected that the amount of medication in your body after taking the nasal spray will be 43 times lower than taking the medication as a tablet and side effects are anticipated to be less likely. The frequency of these side effects is unknown but they are uncommonly reported and unexpected when using the nasal spray. Allergic reaction (e.g. patches of skin redness (erythema), itching and skin rash), nausea, gastrointestinal pain, abdominal pain, gagging, diarrhoea, dizziness, blue colour to skin or lips (cyanosis), excessive sweating (hyperhidrosis) and fatigue.
Not everyone will be able to take the trial medication. Why might I not be able to use the trial medication?	1. You have an allergy to ciclesonide. 2. You have had a live vaccine within last 14 days for example influenza.	1. You have an allergy to niclosamide.

	3. You have severe liver impairment.	
I already take some medications; can I also have the trial medication?	You will not be able to take the trial medication if you already use a daily inhaled corticosteroid. A doctor will decide whether any other medication you are taking may interact with the trial medication. You may not be able to take the trial medication because of this.	You will not be able to take the trial medication if you already use niclosamide.
Is the trial medication vegan friendly and alcohol-free?	Ciclesonide does not contain any meat derivatives or animal products. It does contain a small amount of ethanol (alcohol) and should not be used near heat or an open flame.	Niclosamide does not contain any meat derivatives, animal products or alcohol.

While you are taking a trial medication, we will collect information from your care home about any side effects you may experience. Please speak with your care home team if you have any concerns about the trial medication you are asked to take or experience anything you think is a side effect.

26.How to contact us

Contact details for the research team;

- Email protect-trial@nottingham.ac.uk
- Phone 0115 748 7710