Prophylactic Therapy in Care Homes Trial (PROTECT-CH)

Legal Representative Information Sheet

Final v2.0, 01-Jul-2021

IRAS Project ID: 294832

1. The person you are representing is 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 the person you are representing would like 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.
- We feel that the person you are representing is unable to decide for themselves whether to take part. To help decide if they should join the trial, we would like to ask your opinion on whether or not they would want to be involved. We would ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about taking part in research. These should take precedence.
- Please take time to read this information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or you would like more information.
- If you are unsure about taking the role of legal representative you may seek independent advice. We will understand if you do not want to take on this responsibility.

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 the person I am representing take part in this trial if they've 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 the person you are representing from catching and passing on the coronavirus. So, it's important we continue to look for more preventative medications.

5. Why has the person I am representing been invited to take part?

The person you are representing has been invited to take part because they live in a UK care home which is taking part in this trial.

6. Does the person I am representing have to take part?

No. It is up to you to decide whether the person you are representing takes part in the trial or not. A member of the research team will be able to answer any questions you may have.

If you decide they should not take part, their care will continue in the normal way.

If you decide they should take part, you are free to change your mind at any time and without giving a reason and this will not alter their care in any way.

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 the person you are representing 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 risk of side effects which we will discuss with you. We will also use the information we collect from the GP of the person you are representing and talking with their care home staff to decide whether a particular trial medication would be suitable for them to have. If the person you are representing is allocated the trial medication we will ask them and their care home about any side effects they may experience and will be vigilant about any problems they may incur.

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.

The care home will be allocated a particular trial medication. If you agree that the person you are representing can take part, they will either have their usual care plus a trial medication for 6 weeks or carry on with their 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 the care home, can choose what the person you are representing will receive. This will be decided by a computer.

If you agree to the person you are representing taking part:

1. You will be asked to sign a Consent Form for them to be part of the trial. We will

confirm with the care home that you are able to act as legal representative for this person.

2. With your permission, we will inform the GP of the person you are representing about their participation in this trial. We would also like to access their medical records, including those held by their GP. We would like information about their medical history and the medications they are taking. This will help us understand which of the trial medications they can have.
3. Care home staff will be asked to complete 2 questionnaires with details about the health of the person you are representing.
4. The person you are representing 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 24.
5. The researchers will collect some information from the care home about the trial medication received and whether this has made a difference to the health of the person you are representing. We will also collect some information from national databases and trusted third parties about their ongoing health status and current co-morbidities pertinent to their taking part in the trial including some personal information. This may include information from their medical records over a number of years and their current-COVID vaccination status.
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 the person I am representing gets usual care what does this mean?

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

11. If the person I am representing gets a trial medication what does this mean?

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

12. What if I want the person I am representing to stop taking a trial medication?

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

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

13. What if I would like the person I am representing to take part in the trial but they cannot take the trial medication?

If it's decided that the person you are representing cannot take the trial medication allocated to their care home then they will still be able to take part in the trial. They will continue to receive care as normal and we would like to continue to collect information about their 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 each care home. You will be given information on any new trial medications and we will ask you if you feel that the person you are representing would be happy to remain involved. There will be a period of time in between taking any trial medications.

15. 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.

16. What will happen if I don't want the person I am representing to carry on with the trial?

You are free to withdraw the person you are representing at any time, without giving any reason, and without your or their 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 for the person you are representing to stop taking part in the trial, or they are not eligible to take the allocated trial medication, we would like to continue collecting information about their health from central health service records. If you do not want this to happen, tell us and we will stop.

17. How will information about me and the person I am representing be used?

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

The person you are representing will be given a unique number to replace their personal

details. However, sometimes we need to be able to link the research data with the medical records of the person you are representing, for example using their name/date of birth/NHS number. We will need this information:

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

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

18. How will information about me and the person I am representing be stored and shared?

All information about you and the person you are representing 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 the person you are representing as a research participant.

When the trial has finished, some of the data will be kept so the results can be checked and each care home can be told the results. We may also carry out further analyses using data from the person you are representing to answer other research questions. We will ensure reports are written in such a way that no-one else could work out that you or the person you are representing 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. We are collaborating with researchers from the Universities of Edinburgh, Cardiff, Surrey, Cambridge, Dundee and Queen's Belfast. 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 or the person you are representing 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 and that of the person you are representing.

19. What are my choices about how my information and that of the person I am representing is used?

The person you are representing can stop being part of the trial at any time, without giving a reason, but we will keep information about them that we already have. We need to manage their 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 the person you are representing. After 7 years data from the person you are representing that was collected during the trial will be disposed of securely.

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

You can find out more about how we use information from the person you are representing:

- 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

21. 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 the interests of the person you are representing. 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.

22. What if relevant new information becomes available?

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

23. What happens at the end of the trial?

We will inform each 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. The person you are representing will not be identified in any publication.

24. What are the trial medications?

The 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 are swallowed. 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 does the person I am representing 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 with help the person you are representing 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 does the person I am representing need to take the trial medication?	They will be asked to take this medication for 6 weeks.	They 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.	As Niclosamide is normally taken as tablets to swallow, we do not know what the side effects of the nasal spray will be.

	Uncommon: Nausea, vomiting, a bad taste, skin reactions or dryness at site of the inhaler or mask, oral fungal infections, headache, dysphonia (abnormal voice), cough after inhalation, paradoxical bronchospasm (tightening of the airways), eczema and rash, nasal discomfort, nose bleeds (epistaxis) **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	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 the body after using 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 the person I am representing not be able to use the trial medication?	1. They have an allergy to ciclesonide. 2. They have had a live vaccine within last 14 days for example influenza. 3. They have severe liver impairment.	1. They have an allergy to niclosamide.
The person I am representing already takes some medications; can they also have the trial medication?	They will not be able to take the trial medication if they already use a daily inhaled corticosteroid. A doctor will decide whether any other medication they are taking may interact with the trial	They will not be able to take the trial medication if: 1. They already use niclosamide.

	medication and they can therefore not use the trial medication in addition.	
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 the person you are representing is taking a trial medication, we will collect information from their care home about any side effects they may experience. Please speak with their care home team if you have any concerns about the trial medication they are asked to take or if they experience anything you think is a side effect.

25. How to contact us

Contact details for the research team;

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