



# PROTECT-CH

Prophylactic Therapy in Care Homes Trial

**Therapy Training Module:**

**Ciclesonide**

# Introduction

## Who should complete this training?

You are asked to complete this training because your role in the trial is one of the following:

- Care home manager
- Care home research champion
- Care home staff/Research Nurses who are responsible for the administration of the PROTECT-CH trial medication

**This training module covers the administration of ciclesonide only**

# Purpose of Training

- To provide an overview of PROTECT-CH ciclesonide medication
- To explain what PROTECT-CH ciclesonide medication is, how it looks, when it should be given each day and how it will be administered
- To explain how and when you will receive the PROTECT-CH ciclesonide medication from the central pharmacy and information on storage and handling
- To provide important safety information about PROTECT-CH ciclesonide medication

# Purpose of Training

- PROTECT-CH ciclesonide medication is formulated as a liquid inside an inhaler. Ciclesonide is an inhaled drug which is administered with a spacer unit, which is a tube that has a mouthpiece or mask at one end and the inhaler at the other. The spacer ensures the drug enters the lungs more effectively, by delaying the time it takes to enter the body.
- You will be trained on the use of inhalers and spacers, and specific risks of bleeding including central serous chorioretinopathy, risk of airway obstruction from aspiration of loose objects (e.g. dentures) and adrenal crisis.

# What happens if you have a confirmed case of COVID-19?

- If a resident or member of staff has a positive COVID-19 test (PCR or lateral flow or equivalent) complete the outbreak form in the trial database (REDCap).
- For each resident that is eligible for the trial upload a copy of their Medicine Administration Record (MAR) (last 7 days) to the PROTECT-CH documents vault.
- You will receive a notification informing you of what treatment your care home has been assigned and confirmation if any medication will be prescribed.

## What to do if the positive lateral flow test is followed by a negative PCR test?

- If a resident or member of staff has a positive lateral flow COVID-19 test this will be followed up with a laboratory PCR test.
- If the PCR test result is negative contact the trial team as soon as possible.
- A negative PCR test result means the administration of the PROTECT-CH ciclesonide medication is no longer required, unless another resident has become positive in the meantime.
- If you have received the PROTECT-CH ciclesonide medication but have not started administration please quarantine the trial medication and wait for further instructions.
- If you have started administering the PROTECT-CH ciclesonide medication do not give any further doses to any participants and quarantine the trial medication until you receive further instructions.

# Overview of PROTECT-CH ciclesonide medication

- Ciclesonide is a new-generation corticosteroid with high local anti-inflammatory properties, which is used for the treatment of bronchial asthma.
- Ciclesonide might be useful to prevent the spread of COVID-19 as it reduces the ability for the coronavirus to produce new virus particles and it reduces inflammation in the nose and lungs.
- The main aim of this clinical trial is to test treatments, including ciclesonide, to find out if they reduce the risk of care home residents catching the virus that causes COVID-19.

# Supply of PROTECT-CH ciclesonide medication

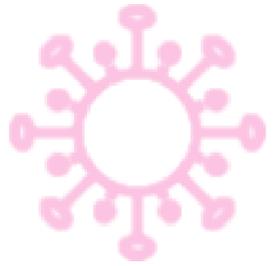
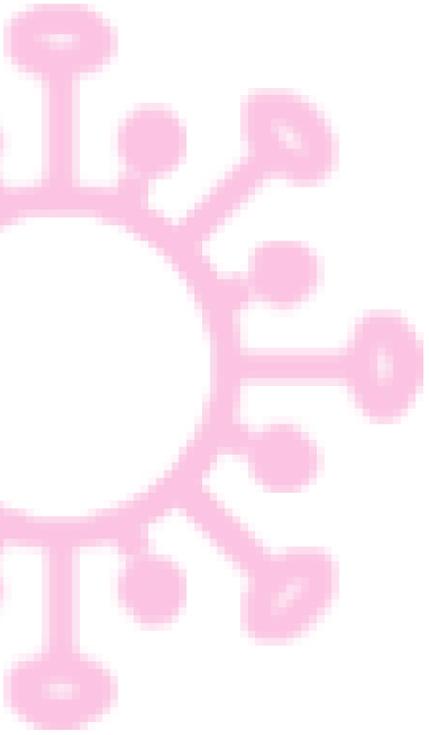
- Following an outbreak, if your care home is randomised to ciclesonide the trial team will arrange for the central pharmacy to ship the PROTECT-CH ciclesonide medication and the spacer devices to the care home in **one** shipment.
- A responsible member of the care home staff will need to sign for the package(s) upon arrival.
- **Care home staff should check what they have received is correct and there are no broken/damaged items**
- Care home staff should register receipt of the package(s) and/or report any damaged/missing items by **logging into the system/calling NCTU/emailing NCTU?**
- Detailed guidance on what to do when the medication arrives and at the end of the trial will be provided in the shipment package

# Supply of PROTECT-CH ciclesonide medication

- Each eligible participant will require 2 inhalers, a spacer and a mask (or mouth-piece) for the 6 weeks duration of treatment. **ADD IMAGE OF HOW PACKAGE WILL LOOK**
- The participant's name will be entered on the label on each inhaler and the cardboard packaging.
- **ADD IMAGE OF LABEL**
- Care home staff will be asked to label all device parts, including spacer, mask and mouth-piece (if used) with the participant's name in permanent marker.

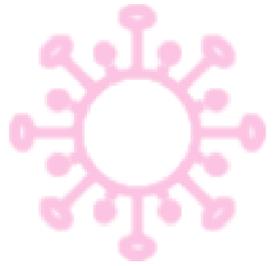
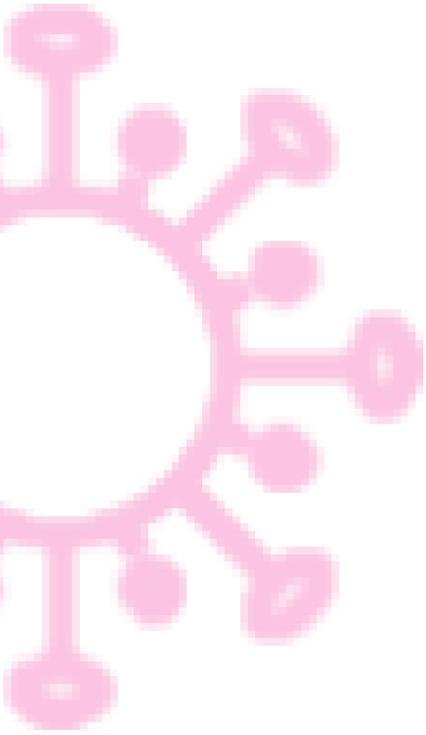
# Storage and Handling

- Upon receipt, store the medication at room temperature as per usual care home practice.
- After each use the inhaler should be placed back inside its cardboard packaging with the mouthpiece at the top ready for next use.
- Ensure the participant finishes the inhaler they are using before opening the second.
- Storage of the spacer devices should also be as per usual care home practice.



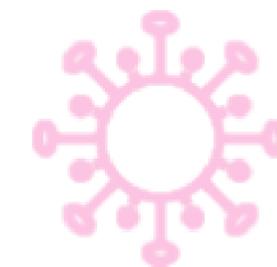
# Administration

- PROTECT-CH ciclesonide medication will be administered using an inhaler, which will be attached to a spacer device (refer to dosing instructions for more information - **ADD LOCATION**).
- The spacer device will connect to a mask which should be placed over the nose and mouth. If the participant does not want to use a mask, a mouth piece can be used as an alternative (refer to dosing instructions for more information).
- Administration can either be done by the participant or by a suitably trained person



# Administration

- Multiple puffs will be required to achieve the correct dose which will be 3 x 160 µg a day for 6 weeks (1 puff targeted at the nose, 2 puffs at the mouth).
- Try and administer the dose at the same time each day as part of your normal drug round e.g. 07:00 or 19:00.



# Administration



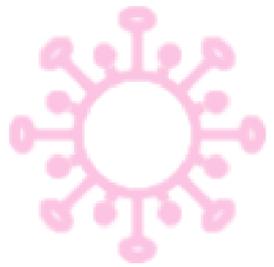
Ciclesonide inhaler



Inhaler attached to spacer and mouthpiece



Inhaler attached to spacer and mask



# Cleaning

- The spacer devices should be cleaned weekly (refer to dosing instructions for further information on how to clean the device).

# Record keeping & Documentation

- You will be provided with a trial specific Medication Administration Record (MAR) which will need to be completed for each participant.
- You will be required to log in to the trial database (REDCap) using your login details previously provided and enter the date PROTECT-CH ciclesonide medication was started.
- We will also ask that on a weekly basis you enter details from the trial-specific MAR chart on doses of treatment given and if any doses were missed and main reason(s) for missed dose.
- A weekly email reminder will be sent to the care home to enter this data.

# Disposal

Do not throw away any empty inhalers, spacer devices or trial specific MARs until you receive confirmation from the trial team.

At the end of the clinical trial, disposal of any unused PROTECT-CH ciclesonide medication should be as per standard care home practice, i.e. local pharmacy.

# Safety and Deviations

Ciclesonide is currently approved to be used in the UK to treat asthma. At the dose administered there may be occasional side effects, which are listed on the next slide.

Safety reporting in the trial will focus only on those events that could be related to the trial medication, ciclesonide, are serious in nature and are unexpected (either the event itself or in severity).

See the next slide for the known side-effects of Ciclesonide.

# Safety and Deviations

## Incidence

## Side-effects

**Uncommon  
(>1/1,000, <1/100)**

Nausea, vomiting\*, bad taste, application site reactions, application site dryness, oral fungal infections\*, headache\*, dysphonia, cough after inhalation\*, paradoxical bronchospasm\*, eczema and rash, nasal discomfort, epistaxis

**Rare or very rare  
(>1/10,000 -  
1/1,000)**

Palpitations\*\*, abdominal pain\*, dyspepsia\*, angioedema, hypersensitivity, hypertension

**Unknown**

Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children)

\*similar or lower incidence when compared with placebo

\*\* palpitations were observed in clinical trials in cases mostly confounded with concomitant medication with known cardiac effects

# Safety and Deviations

- Serious Adverse Events (SAEs) are defined as any untoward medical occurrence that at any dose
  1. Results in death
  2. Is life-threatening
  3. Requires hospitalisation or prolongation of existing hospitalisation
  4. Results in persistent or significant disability or incapacity
  5. Consists of a congenital or birth defect.

# Safety and Deviations

- You will be required to complete the safety training module before reporting any SAEs.
- SAEs should be documented and reported from the date of first administration of PROTECT-CH ciclesonide medication until the end of the treatment period. (refer to safety training module).
- Each care home will be required to enter SAEs into a trial database (REDCap, SAE form). The person completing the report will include sufficient details of the event to facilitate the assessment of relatedness by a member of the national team of medically qualified Principal Investigators.
- Should a participant's GP become aware of an SAE during the reporting period, they may report the event via the same process. A Principal Investigator will review the information in the SAE report and will liaise with the reporting care home or GP to obtain further information where necessary.
- Add info on deviations/violations

# Important information

- If a resident tests positive for COVID-19, then trial treatment should continue but it will stop if the resident is admitted to hospital.
- When a resident returns to their care home the treatment will continue up to the point that they originally would complete treatment.
- If a dose is missed do not administer a double dose, continue using according to the administration instructions
- If too much PROTECT-CH ciclesonide medication is administered contact the trial team
- Use your standard drug treatment procedures when handling ciclesonide, e.g. wear gloves and PPE as standard for your care home.

## In this module, we have covered the following:

- Purpose of training
- What happens when you have a confirmed case of COVID-19
- What to do if following a positive lateral flow test the PCR test result is negative
- Overview of PROTECT-CH ciclesonide medication
- Supply of PROTECT-CH ciclesonide medication
- Storage and handling
- Administration
- Cleaning of the spacer device
- Record keeping & documentation
- Disposal/returns of any unused PROTECT-CH ciclesonide medication and/or spacer device
- Safety and deviations
- Important Information

## Before you engage in any trial-related activities, please ensure:

- You have completed the PROTECT-CH COVID-19 Outbreak Guidance Training Module.
- You have completed the PROTECT-CH Therapy Training module: Ciclesonide (depending on the randomisation result)
- You have completed the PROTECT-CH Safety Training Module
- Check you are delegated to administer PROTECT-CH ciclesonide medication on the trial delegation log. (You need to have added the relevant task number next to your name in the delegation log and that needs to have been signed off before you are involved in the delivery of the PROTECT-CH ciclesonide medication.)

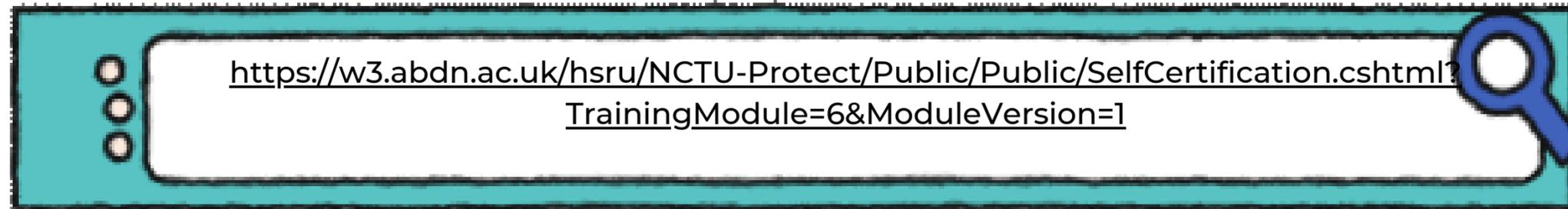
Thank you for watching!

You have now completed the  
**Ciclesonide**  
Therapy Training Module



Please remember to complete your self certification form  
to confirm you have undertaken this training.

This can be found at:



Or you can access it  
via mobile here:



Please get in touch with us  
if you have any questions:



[protect-trial@nottingham.ac.uk](mailto:protect-trial@nottingham.ac.uk)



0115 74 87710

*Thank  
you*