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PROTECT-CH
Prophylactic Therapy in Care Homes Trial

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Therapy Training Module

Niclosamide

Final Version 1.0 15-Jul2021

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 responsible for the administration of the PROTECT-CH trial medication

This training module covers the administration of niclosamide only

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Purpose of Training

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

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

- **This training is specific for care homes assigned to the treatment niclosamide.**
- 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.

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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 trials team as soon as possible.
- A negative PCR test result means the administration of the PROTECT-CH niclosamide medication is no longer required unless another resident has become positive in the meantime.
- If you have received the PROTECT-CH niclosamide medication but have not started administration please quarantine the medication and wait for further instructions.
- If you have started administering the PROTECT-CH niclosamide medication do not give any further doses to any participants and quarantine the medication until you receive further instructions.

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Overview of PROTECT-CH niclosamide medication

- Recent studies have shown niclosamide may be a potential treatment for viral infections such as SARS-CoV-2 (COVID-19).
- Niclosamide reduces the ability for the coronavirus to produce new virus particles. It also reduces inflammation in the nose.

- Nicolsamide is not licensed to treat COVID-19 but is approved and marketed in many countries to treat tapeworm.
- It is normally taken as tablets that you swallow, but a nasal spray has now been developed to find out if it can prevent COVID-19 in patients at particularly high risk of infection.
- This trial will use the nasal spray.

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Supply of PROTECT-CH niclosamide medication

- Following an outbreak, if your care home is randomised to niclosamide the trial team will arrange for the central pharmacy to ship the PROTECT-CH niclosamide medication 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.
- Care home staff should register receipt of the package(s)
- Detailed guidance on what to do when the medication arrives will be provided in the shipment package.

Supply of PROTECT-CH niclosamide medication

- Each eligible participant will be prescribed 3 bottles of Niclosamide ethanolamine (UNI911) 1% nasal spray solution (10mg in 1mL)
- This will cover the 6 weeks duration of treatment.
- Each bottle will be labelled with the participant's name and a unique identification number.

Example label:

PROTECT-CH: For Clinical Trial Use Only - retain all medicine containers until trial complete.
EudraCT No: 2021-000185-15
Niclosamide ethanolamine (UNI911) 1% (10 mg in 1 mL) nasal spray 8.5 mL
Batch Number: XXXXXX
Name of participant: XXXXXXXXXXX
Participant ID: XXXXXX
Sponsor: University of Nottingham (Tel: XXXXXXXXXXX)

Storage and Handling

Need updated image once availble

- Upon receipt, store the medication at room temperature as per usual care home practice.
- When not in use store the nasal sprays upright.
- After each use the nasal spray should be placed back inside its cardboard packaging ready for next use.
- Ensure the participant finishes the nasal spray they are using before opening a new bottle.
- Each nasal spray is only to be used by the individual named on the label and should not be shared.

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Administration

- Participants will be administered 140µL (**1 spray**) into **each** nostril **twice daily** for **6 weeks**.
- Try and administer the doses at the same times each day as part of your normal drug round, e.g. 07:00 and 19:00.
- Administration can either be done by the participant or by a suitably trained person.
- Make sure each nasal spray is empty before starting the next as no spare nasal sprays are provided in the shipment.
- The solution is red-orange in colour and may cause staining on hands or clothes.
- Nasal secretions may also be red in colour.
- When not being used the nasal spray should be stored in the labelled carboard container in an upright position.

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Administration

1) Check the participant details on the label of the nasal spray are correct. Remove the cap from the nasal spray.

2) Hold the bottle with 2 fingers on the shoulders of the spray pump and your thumb on the bottom of the bottle.

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Administration

3) Step 3 is only required for the first use of a new bottle (otherwise skip to step 4):
Press downwards with your top two fingers and release (spraying into the air not nostril). Repeat this 2-3 times.

4) Insert the tip of the nasal spray slightly into the nostril and press on the other side of the nose with one finger. Then push the spray pump down until it will not go any further.

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Administration

5) Repeat step 4 in the other nostril.

6) Put cap back on the nasal spray and put back into carboard packaging ready for next use.

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Cleaning

- There is no requirement to clean the nasal spray after each use.

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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 into the trial database (REDCap) using your login details previously provided and enter the date the PROTECT-CH niclosamide 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 reminder will be sent to the care home reminding you to enter this data.

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Disposal

Do not throw away any empty nasal sprays or trial specific MARs until you receive notification from the trial team.

You may be asked to return any unused PROTECT-CH niclosamide medication at the end of the trial.

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Safety and Deviations

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

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

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Safety and Deviations

- Niclosamide has previously been administered as oral tablets. The side effects of the nasal spray are not yet known.

- The occasional side effects reported for the oral tablet are detailed below. These are unlikely when using the nasal spray due to the much lower dose:

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.

- Side effects sometimes reported with nebulization procedures include **bronchospasm and coughing**

- Although not known we anticipate the following side effects may be experienced: **nasal itching, nasal irritation, nasal crusting, nasal drip and nasal bleed.**

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Safety and Deviations

- Serious Adverse Events (SAEs) are defined as any untoward medical occurrence that at any dose

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital or birth defect

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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 niclosamide medication until the end of the treatment period.
- 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.

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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 the care home they can continue treatment 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 niclosamide nasal spray is administered contact the trial team.
- If the participant sneezes immediately after receiving the dose do not repeat the dose.

- Use your standard drug treatment procedures when handling niclosamide, e.g. wear gloves and PPE as standard for your care home.

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In this module, we have covered the following:

- Purpose of training
- What happens when you have a confirmed case of COVID-19
- Overview of PROTECT-CH niclosamide medication
- Supply of PROTECT-CH niclosamide medication
- Storage and Handling
- Administration
- Cleaning
- Record keeping & documentation
- Disposal
- Safety and deviations
- Important information

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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: Niclosamide (depending on the randomisation result).
- You have completed the PROTECT-CH Safety Training Module
- Check you are delegated to administer PROTECT-CH trial 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 administration of niclosamide).

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Thank you for watching!

You have now completed the

Niclosamide

Therapy Training Module

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

This can be found at:

https://w3.abdn.ac.uk/hsru/NCTU-Protect/Public/Public/SelfCertification.cshtml?TrainingModule=6&ModuleVersion=1

Or you can access it via mobile here:

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

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