OPACE TRIAL PARTICIPANT INFORMATION SHEET SUMMARY

CCTU/TPL002V10 Approved 30/05/2022 Reviewed 30/05/2022

OPACE TRIAL
OPtimising Azithromycin prevention treatment in COPD to reduce Exacerbations

OPACE TRIAL: Optimising azithromycin prevention treatment in COPD to reduce exacerbations

This information sheet is intended to provide summary information regarding the OPACE trial. Please refer to the main participant information sheet for a more detailed description of the trial and information on how your data will be stored and used. You will be given a copy of it if you decide to take part in the trial. This main information sheet, together with a video is available at the link below if you have internet access. We can also send it in the post.

You can access the video here via this link https://opacecopd.org.uk/participant-information/ or scan the QR code below.

MORE INFORMATION IS AVAILABLE AT www.opacecopd.org.uk

Thank you for your time and welcome to the OPACE trial. You are being invited to take part in this clinical trial because you have a condition called chronic obstructive pulmonary disease (COPD) and take long term azithromycin or a similar antibiotic for this. If you decide to take part in this trial, you will be playing an important part in understanding more about how to best treat and manage COPD for the future. Without the help of people like you, volunteering to take part in clinical trials like this, treatment for COPD would not be able to progress. Thank you. Please take the time to read the following information carefully and ask us if you have any questions.

1. What is the purpose of the trial?

To improve treatments for people with COPD we need to find out if there are benefits of long-term azithromycin (beyond 1 year treatment) or benefits in a trial of stopping it.

Azithromycin is prescribed for some people with COPD to reduce the number of COPD 'flare ups' (also called 'exacerbations') they may experience in the first year of treatment. Much less is known about the longer-term benefits of continuing azithromycin for longer than 12 months or benefits in undertaking a test of stopping it. Around the UK, we already have some patients staying on the medication for a long time, and others stopping earlier.

It is important to find out if azithromycin is effective at reducing flare-ups longer-term because often patients still get a flare-up; despite being on treatment. Azithromycin treatment increases antibiotic resistance and azithromycin, like all drugs, can cause side effects. Therefore, if there are benefits to continuing it longer-term or benefits to a test of stopping it with plan to restart at any time if needed, this is really important information to know and what we are finding out in the trial.

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2. What is the drug being tested?
Azithromycin will be compared to a placebo (dummy drug).

3. Why have I been invited?
You have been invited to participate in this trial because you have COPD and are prescribed long term treatment azithromycin or similar antibiotic. As part of the trial, you will be joining about 600 participants with COPD who are on long-term antibiotics from GP practices and hospitals across the UK.

4. Do I have to take part?
Participating in this trial is **completely voluntary**. If you decide to participate you will be asked to sign an Informed Consent Form. However, you are still free to change, reduce or completely withdraw your participation after you agree to join this trial and can do so at any time. Any period of participation in the trial, no matter how short, is valuable and greatly appreciated, and will help us with much needed evidence we hope to gain. If you want to stop the trial treatment or withdraw from the trial early, then you are free to do so without it affecting your future care or medical treatment.

5. What will happen to me if I take part?
If you take part you will be randomly allocated by a computer system to a trial medication group which will be either:

- Azithromycin (provided as a trial medication but will match your routine prescription), or
- Placebo (dummy drug).

The trial medication will be delivered to your home.

You will be part of the trial and under trial team follow up for about 20 months.

You will have **three trial visits:** one at baseline on entering the trial, then at 12 and approximately 20 months. The first trial visit may be up to 1 hour long. Visits 2 and 3 may last about 30 minutes. We will also schedule some interim phone calls at 3-6 months intervals to see how you are doing by asking some questions about your COPD and health.

There is a blood test and breathing test at baseline **only if you are able to and if this is possible to arrange.**

You will be given a diary card to record information about your flare-ups (exacerbations).

We can arrange for any or all the trial visits including baseline to be conducted remotely while you are at home (phone or video consultation), if you prefer.

In the trial, either you or your trial team may decide that it is best for you to stop trial medication and restart your standard azithromycin prescription at any time. If you have a flare-up of your COPD (also called an exacerbation), it is important to let us know as we may decide to stop your trial medication and advise you to restart your standard azithromycin prescription. We would still like to follow you up in the trial if this is the case and you are happy for this. However, if you do not want to continue with trial scheduled follow up either, with your consent we can use routinely collected healthcare information for trial purposes until the end of the whole trial.

We will let your GP (and your hospital team if needed) know you are taking part in the trial. If anything comes up in the trial which may be important for you and your GP to know, we will inform both you

and your GP. You will not need to take your regular azithromycin prescription from your GP whilst you are on trial medication.

6.Sub-study to gain your feedback on your experience of the OPACE trial
An optional sub-study of the OPACE trial to gather feedback on your participation in this clinical trial will also be offered to you. The purpose of this sub-study is to gain important feedback from participants in the trial to help us improve how we conduct future research trials for participants. If you consent to this sub-study, your trial team will send you a questionnaire to complete as a short survey of your experience. This will be done soon after you enter the trial, and possibly at the end of trial.

In addition to these short questionnaires, we are planning to interview by telephone a smaller number of participants for more in-depth feedback. This is optional too. It is a one-off telephone call conducted by the central OPACE clinical team at Cambridge University Hospitals NHS Foundation Trust, and will likely take place around 3 months from enrolment.

7. What are the possible benefits of taking part?

- We cannot guarantee any specific treatment benefits from taking part in this trial, however you will have more frequent monitoring of your COPD and health.
- You may experience fewer azithromycin-related side effects.
- By taking part in this trial, you will be playing an important part in understanding more about how to treat and manage COPD in the future.
- Without you, and others volunteering to take part in clinical trials like this, treatment for COPD wouldn't not be able to progress. Thank you.

8. What are the possible disadvantages and risks of taking part?
You are already on azithromycin or a similar antibiotic and like all drugs, azithromycin can have side effects. Long term azithromycin use increases the risk of antibiotic resistance. A possible disadvantage of taking part may be that you experience a flare-up of your COPD. You can stop trial medication and restart your standard azithromycin at any time in the trial.

9. Expenses & Payment?
We will appreciate your involvement in this trial. We are unable to pay you for participating but we are able to reimburse any reasonable travel and parking costs incurred by your participation in this trial. It is important that you keep any travel related receipts and request a claim form at your trial-related visit, if appropriate. Details of how and when payments will be made are available from the trial team.

10. What if there is a problem?
If you have any concerns about any aspect of this trial you should speak to your trial doctor or nurse who will do their best to answer your questions. You may also contact the Participant Advice and Liaison Service (PALS) at your hospital trial site, or contact the manager at the GP Practice, if the GP practice is your trial site. Please see contact details in **"Further information and contact details"** section. Please also see main information sheet for more details.

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11. How will we use information about you?

In this research trial we will use information from your medical records. We will only use information that we need for the trial. We will let very few people know your name or contact details, and only if they really need it for this trial. Everyone involved in this trial will keep your data safe and secure. We will also follow all privacy rules. At the end of the trial we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write. The main information sheet tells you more about this.

12. What will happen to the results of the trial?

The results will be published in peer reviewed medical journals and used for medical presentations and conferences. The results of the trial will be thoroughly anonymised, and you will not be able to be identified from any of the data published. We will produce a participant leaflet which will explain the trial results once published.

13. Who has reviewed this trial?

All research within the NHS is reviewed 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 the London Central Research Ethics Committee. The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this trial.

14. Further information and contact details

In normal office hours, please contact your OPACE Trial Team: (xxxxx [Generic email & Telephone number (delete if appropriate)]

Principal Investigator, Dr (name), Tel. (#######)

Research Nurse, (Name), Tel. (#####) (update as applicable at local site)

In the event of a medical emergency, please contact 999 or 111