OPACE TRIAL PARTICIPANT INFORMATION SHEET SUMMARY

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OPACE TRIAL
OPtimising Azithromycin prevention treatment in COPD to reduce Exacerbations

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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

You are being invited to take part in a research trial because you have a condition called chronic obstructive pulmonary disease (COPD) and are on long term azithromycin (or an equivalent macrolide antibiotic) for this. 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?

You have a condition called COPD and are prescribed a treatment called azithromycin (or equivalent macrolide antibiotic) to reduce the chance of flare-ups (also called exacerbations) occurring. We currently do not know how best to use azithromycin in COPD, and we need evidence to help guide us how to use it for patients.

We currently don't know whether to advise patients to continue their azithromycin long term or stop taking azithromycin once their COPD has become more stable, or whether to advise them to stop it over the summer when fewer flare-ups tend to occur, restart it in the winter. We also do not know if azithromycin is more effective in some people or more likely to cause side effects in others. Side effects of azithromycin may affect some people. It sometimes can cause heart problems; hearing problems and antibiotic resistance is a concern with long term treatment.

2. What is the drug being tested?

Azithromycin will be compared to either dummy azithromycin (placebo pills), or a combination of azithromycin over the winter (six months of azithromycin from October to March) and dummy azithromycin (placebo pills) over the summer (six months of placebo from April to September).

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 equivalent macrolide antibiotic for COPD flare-ups. You do not need to visit research sites to take part.

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, even if short, is greatly appreciated and valued and will help us with much needed evidence we hope to gain from the trial. 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 (this is done to avoid bias in the trial) to a trial medication arm which will be either:

- Azithromycin (provided as a trial medication but will match your routine prescription), or
- Placebo (dummy azithromycin), or
- Azithromycin in the winter months, placebo in the summer.

Trial medication will be delivered to your home.

You will be part of the trial and under trial team follow up for about 24 months.

You will have **three trial visits:** one at baseline on entering the trial, then at 12 and 24 months. The first trial visit may be up to 1 hour long. Visits 2 and 3 may last about 30 minutes.
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.
The phone calls will be about 10 minutes long. We will telephone you. We will ask you to complete some questionnaires which are about your COPD, symptoms and general mental health.
There is a blood test and breathing test at baseline if this is possible to arrange and only if you are able to.

In the trial, if you have a flare-up or exacerbation, it is important to let us know as we may decide to stop your trial medication and advise you to restart your routine 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 respiratory 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 the trial.

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 research trial will also be offered to you. You do not have to participate in this sub-study, it is optional. 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. In addition, 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?

You may have no personal benefit from taking part in this trial. You will have trial related monitoring and interactions with healthcare professionals during the trial. You may experience fewer azithromycin related side effects. However, the results from this trial will benefit patients with COPD

in the future because it will help us know how best to use azithromycin long term treatment for people with COPD.

8. What are the possible disadvantages and risks of taking part?
The possible disadvantage may be that you experience more flare-ups of your COPD; or you may experience side effects related to azithromycin. You will be followed up during the trial, and it is important to let us know this type of information. We may decide to stop your trial medication because of it.

9. Expenses & Payment?
We are unable to pay you for participating but we are able to reimburse your travel expenses to and from the site for the trial-related visits. 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 teamYou will not receive any payment for participating in this trial, however we can reimburse any reasonable travel and parking costs incurred by your participation in this trial. Up to £30 per visit for travel can be paid for with receipts shown and if the visit is not part of a routine clinical appointment.

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) or equivalent service at your trial research site, or GP Practice Manager (if recruited by a Primary Care Site). Please see main information sheet for more details.

11. How will we use information about you?
In this research study we will use information from your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study 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 ### #######
Research Nurse, ####### (update as applicable at local site)

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