OPACE PARTICIPANT (APPROACHED BY PIC) INFORMATION SHEET & INFORMED CONSENT FORM

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

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.

The OPACE trial stands for '**Optimising azithromycin prevention treatment in COPD to reduce exacerbations**. It is funded by the National Institute for Health and Care Research (NIHR).

This is where your potential involvement in the trial comes in.

By taking 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.

There is also video that also explains the OPACE trial which you may find helpful to view if you have access to the internet. 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

- Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge are the joint Sponsors (responsible organisations) for the OPACE trial being conducted across the UK.

- Section 1 of this information sheet tells you the purpose of this trial and what will happen to you if you take part.

- Section 2 of this information sheet gives you more detailed information about the conduct of the trial.

Section 1: Purpose of the trial and what will happen

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 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 may get a flare-up; despite being on treatment. Azithromycin treatment also increases the risk of 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 really important information to know and what we are finding out in the trial.

Clinical trials are the best way to improve treatments for future patients and we hope to find more information on the best way to make these more accessible and easier for patients to take part.

2. What is the drug being tested?

Long term 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 also 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.

It is important to remember that your health and well-being will be closely monitored by your trial team. If your trial team think your participation in the trial has to change or be stopped, in order to protect your safety or well-being, then this will be explained to you. If you choose not to participate, change your participation or to leave the trial,

your future medical treatment and usual standard of care will not be affected in any way.

5. What will happen if we lose contact with you*?*

We may use telephone, email or post as a means to contact you. We may also contact your next of kin if you have provided the trial team with their contact details.

6. What will happen to me if I take part?

If you agree to take part in this trial, you will be asked to sign the Informed Consent Form at the end of this document and you will be given of copy of this to refer to later. Please don't sign it immediately as we will talk you through it during a telephone/video call consultation.

Because you may be taking part from home, you will have a separate consent and eligibility assessment on the telephone or video call(s) prior to any trial assessments. Once this is completed, the consent form may either be sent back in a stamped addressed envelope or if possible, to arrange and for convenience it may be picked up directly from your home and sent back directly to the trial research site.

Once the consent form is received by the trial team, they will contact you again and confirm if you are still happy to take part in the trial.

Information about the trial medication

If you take part in the trial, you will be randomly allocated by a computer system (this is done to avoid bias in the trial) to a trial medication group, which will be either:

- Azithromycin, or
- Placebo (dummy drug).

To avoid any influence on the results, you and your trial team will not know if you are on azithromycin or placebo. Your trial medication prescription will also match your routine azithromycin prescription regardless of being randomly allocated to Azithromycin or placebo. If necessary, your trial team can find out if you are on azithromycin or placebo.

Please be aware, tablets may vary slightly from your regular azithromycin prescription and may vary slightly in appearance in different batches - this is perfectly normal and is nothing to be concerned about.

- The trial medication will be delivered to your home or preferred delivery address via a central pharmacy. With your consent, only your contact details and trial prescription will be shared securely to the trial's central pharmacy to enable dispensing and delivery of trial medication. This pharmacy will not share any of these details provided and will only use these for the purpose of dispensing and delivering trial medication to your chosen delivery address.

- You will take your standard azithromycin until your trial medication arrives. Once you receive your trial medication, you will take this instead of your standard azithromycin.

- You will be monitored by your trial team throughout the trial. If you have a flare-up (an exacerbation) of your COPD during the trial, please contact your trial team

to let them know. They may decide or you may decide that it is right for you to go back on your standard azithromycin.

- You can decide to stop the trial medication at any time in the trial and restart your standard azithromycin. Please let the trial team know if you decide to do this.

If you stop trial medication and restart standard azithromycin, we would still like to follow you up in the trial if possible. You can either decide this by scheduled follow up or, with your consent, we can use routinely collected healthcare information for trial purposes until the end of the whole trial.

Information about trial visits and assessments

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

You will have **seven trial home consultations performed on the telephone (or video calls):**

- Consultation one at baseline (separate to the consent consultation) on entering the trial, then
- Consultations at about 1 week, 3 months, 6 months, 12 months, 18 months and around 20 months.

The phone calls will be about 10-30 minutes long. We will telephone you. We will ask you about your COPD, symptoms and general health.

We may ask your GP/local hospital for a blood test or breathing test result if available. If we are able to arrange for you to have a routine blood test or breathing test as part of the trial, we will do so.

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 for your general and mental health, we will inform both you and your GP.

7. What will I have to do?

- You will be in the trial for about 20 months.

- It is important that you take the trial medication regularly as directed by your trial doctor.

- We will provide you with a diary to record any COPD flare-ups and you should let us know if possible if you do have a flare-up. Our contact details are at the end of this information sheet.

- If you experience a flare-up, you can decide if you would prefer to restart your standard azithromycin instead of continuing the trial medication. Please let us know.

- We may also decide it is best for you to stop the trial medication and restart your standard azithromycin.

- You will be telephoned during the trial and this can be scheduled at an agreed time/date convenient for you to answer the call.

- If you have any concerns about the trial, please contact us to discuss using the contact numbers at the end of this information sheet.

- If you are feeling unwell, then please seek medical help as you normally would, but let your trial team know when you are able to.

- You should discuss your participation in this trial with any insurance provider you have (e.g. travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate your cover.

8. What are the side effects of the drug being tested and risks of taking them?

You are already on azithromycin or a similar antibiotic.

Azithromycin: is a licensed medication, therefore expected side effects are well known. All medications can have side effects. Below are some of the side effects of azithromycin:

- **Very common** (more than 10 in 100 patients): include diarrhoea, abdominal pain, flatulence, nausea.
- **Common** (less than 10 in 100 patients) include: vomiting and heart burn, loss of appetite, dizziness, rash, itching headache, change in taste, burning/tingling sensation, visual impairment, joint aches, fatigue, blood test changes, deafness (this could be irreversible).
- **Uncommon** (less than 1 in 100 patients)**:** abnormal blood tests, gastrointestinal symptoms, liver inflammation, ringing in the ears, vertigo, palpitations, infection including thrush, numbness, drowsiness, skin disorders, allergic reaction, heart rhythm abnormalities.
- Long term azithromycin use increases the risk of antibiotic resistance. This means bacteria change over time developing resistance to the antibiotic and the antibiotic becomes less effective at treating infection. This makes it harder to treat infections.

Placebo: the placebo (dummy pills) used in this trial will not contain any active ingredients. There are no known side effects of the placebo.

- A possible disadvantage of taking may be that you experience a flare-up of your COPD. However, you can restart your standard azithromycin at any time in the trial. Side effect(s) related to azithromycin may also be a possible disadvantage. These can include heart rhythm issues and antibiotic resistance. Antibiotic resistance occurs when long use of an antibiotic causes bacteria to change, making the antibiotic ineffective in treating the infection.

9. What are the possible benefits of taking part?

- We cannot guarantee any specific treatment benefits from taking part in the 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.

10. What are the alternatives for treatment?
Standard treatment at the suggestion of your doctor or nurse can be:
- continuing azithromycin long term treatment or
- stopping it

We currently have no information or evidence on the effects of these approaches, which is why we are doing this trial.

11. Pregnancy and contraception information?
Although this may not apply to you, we have to explain to everyone the following:
Although azithromycin is considered safe in pregnancy, women who are planning pregnancy, or are pregnant or breast feeding should not take part in the trial.

12. What happens when the trial stops?
When the trial has stopped, if you are still on trial medication at the end of the trial, you will return to standard treatment with your regular prescription of azithromycin if advised to restart this by your doctor or nurse. This prescription will be provided either by your local pharmacy or hospital pharmacy.

13. Expenses & Payment?
As a token of our appreciation of your participation in the trial, we will provide an amazon gift card of £5. We will phone you for your trial follow ups and can phone you back when you call us (if needed), to try and avoid putting expenses on your phone bill.

14. 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. It is also included in the Informed Consent Form below.

- 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.

- The sub-study includes an optional survey and an optional telephone interview. If you prefer, you can consent to the survey only.

- If you consent to the sub-study survey, your trial team will provide you a questionnaire to complete about your experiences soon after entering the trial, and possibly at the end of the trial.

- The survey is anonymous and does not require any identification. It will ask about your experience with taking part in the OPACE trial, your age, ethnicity and, whether you have a disability or not. You can select 'prefer not to answer' for any question.

- The telephone interviews are also optional and will involve a smaller number of participants for more in-depth feedback. It is a one-off telephone call and will likely take place around 3 months from enrolment. It is anticipated the interview will take about 20-30 minutes. We will arrange with you a convenient time to telephone you. If you consent to the interview this will be conducted by the central OPACE clinical team at Cambridge University Hospitals NHS Foundation Trust.

- To enable the team to contact you to conduct the interview, your contact details will be sent via a secure email from your local site to the central OPACE clinical team based at Cambridge University Hospitals NHS Foundation Trust. If you consent to participate, the call will be recorded to allow us to analyse themes that may be important regarding participants' experiences of taking part in the research trial. We will store your audio file, which will be password protected, on a secure NHS computer until a script of the file is made. In the script, any identifiable details for example, your name(s) will be removed. The audio file will then be destroyed, and the anonymised script will be stored in a password protected file on a secure NHS computer.

Section 2: Trial Conduct

15. What if new information becomes available?

Sometimes during the course of a trial, new information becomes available which might affect your decision to continue participating in this trial. Your trial team will contact you to discuss any new information which might affect your decision to continue in the trial. If you still decide to continue in the trial, you will be asked to sign a new Informed Consent Form.

16. What if I decide to change or stop my participation in the trial?

If you want to stop the trial medication or withdraw from the trial early, then you are free to do so without it affecting your future care or medical treatment. You have the options of:

- Stopping the trial treatment (can restart standard azithromycin) but continuing to have some or all of the scheduled trial follow ups and electronic healthcare data collected.
- Stopping trial medication (can restart standard azithromycin) and scheduled trial follow ups but you allow the team to continue to collect data from e-healthcare records, which would have no burden or input required from you.
- Withdrawing from the trial completely, in which case no more data will be collected about you at all, but data collected up to that point will still be used in trial analysis.

If you decide that you do not wish any more information to be collected about you, feel free to say so. However, please bear in mind that the de-identified information that has been collected up to that point will continue to be analysed by the research team.

Your trial team may also choose to withdraw you from the trial treatment if they feel it is in your best interests.

17. What if there is a problem?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. 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.

In the event that something does go wrong, and you are harmed by taking part in the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust or the University of Cambridge. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The University has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this.

Cambridge University Hospitals NHS Foundation Trust, as a member of the NHS Clinical Negligence Scheme for Trusts, will accept full financial liability for harm caused to participants in the trial caused through the negligence of its employees and honorary contract holders. There are no specific arrangements for compensation should a participant be harmed through participating in the trial, but no-one has acted negligently.

The University of Cambridge will arrange insurance for negligent harm caused as a result of protocol design and for non-negligent harm arising through participating in the trial.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this trial, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Participant Advice and Liaison Service (PALS) or equivalent service at your trial research site. Please see the contact details in the 'Further information and contact details' section at the end of this information sheet.

18. How will we use information about you?

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the joint Sponsors for this clinical trial. Reference to 'we' in this section means the sponsor and not the local site.

We will need to use information from you, your medical records and your GP for this trial. This information will include your:

- NHS number,
- initials
- name,
- date of birth,
- contact details, including post code

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead, meaning your data will have been de-identified.

Cambridge University Hospitals NHS Foundation Trust responsible for looking after your information. We will keep all information about you safe and secure by:

- Limiting who can access your data so only personnel who have been given permission / authorisation may access it
- Keeping paper copies of your data in locked filing cabinets in restricted access areas
- Keeping your electronic data on secure computers that are password protected

International transfers

Your data will not be shared outside the UK.

UK NHS England / Equivalent in devolved nations
As part of your participation in the OPACE trial, we will send your name, date of birth, NHS number and postcode to NHS England (or other central NHS bodies) who can link this information to your centrally held records. NHS England can provide the trial with relevant health information about trial participants, such as those who have died, including the date and cause of death (on behalf of the Office of National Statistics) and information on your hospital attendances. Your health data information will be requested for the duration of the trial only, i.e., up to the close of the trial.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

We will keep your trial data for a maximum of 5 years. The trial data will then be fully anonymized and securely archived or destroyed.

19. What are your choices about how your information is used if you withdraw from the trial?

- You can change or stop taking part in the trial at any time, without giving a reason, but we will keep information about you that we have already collected.
- If you choose to completely stop taking part in the trial (stop treatment and follow up), we would like to continue collecting information about your health from central NHS records, your hospital, and your GP. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the trial. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial.

  This is optional, and should you not wish to be approached about future research studies and/or trials, you will still be able to participate in the OPACE trial.
  If you agree, it means that you are allowing our researchers to keep your contact information and use it for the purpose of contacting you if they think you might

be suitable for a particular research study or trial. It is possible that they may not contact you at all, or they may contact you about a study or a trial that's not directly relevant to your symptoms. If you agree to be approached, there is no commitment to take part in any particular research study or a trial and you can also let us know at any point if you change your mind and no longer want to be approached about future research. Any future research we contact you about will have received approval from an Ethics Committee.

20. Where can you find out more about how your information is used?
You can find out more about how we use your information:

- At www.hra.nhs.uk/patientdataandresearch
- Alternatively. visit, for Cambridge University Hospitals NHS Foundation Trust: https://www.cuh.nhs.uk/participant-privacy/.
  For University of Cambridge:
  https://www.medschl.cam.ac.uk/research/information-governance or email The Information Governance team at: researchgovernance@medschl.cam.ac.uk
- By asking one of the research team: see contact details at the end of this form
- by sending an email to cuh.gdpr@nhs.net

21. 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. We will also publish results on the website. Your trial team will be able to provide this to you.

22. Who is funding the trial?
The trial is being funded by the NHS NIHR (National Institute for Health and Care Research).

23. 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.

24. Further information and contact details

In normal office hours, please contact:
Principal Investigator, Dr ### ######
Co-Investigator, ### ######
Research Nurse, ######
(update as applicable at site)

Your trial [Patient Advisory Liaison Service (PALs)/equivalent service or GP Practice Manager – edit as appropriate] contact details are:

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

On the next pages are two Informed Consent Forms. These are provided together with this Participant Information Sheet Version ## Dated [###] to show what the consent form looks like and what it includes.

Please do not fill them in yet, until your consent appointment has been booked.

Two copies of the informed consent form are provided with this pack, as your consent consultation will be conducted remotely. You will keep one signed consent form and will post back/arrange send back of the other signed consent form.

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Principal Investigator: [Printed name to be inserted]
Site: [Printed name to be inserted]
Participant ID Number: _____

	If you agree with each sentence below, please initial the box	**INITIALS**
1	I have read and understood the Participant Information Sheet version ##, dated #### for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected, and that any data and samples already collected or tests already performed will continue to be used in the trial as described in this information sheet.	
3	I understand that by participating in this trial, I will need to stop my standard azithromycin or similar long-term antibiotic and take trial medication instead. However, I can restart my standard azithromycin or similar long-term antibiotic if I stop taking trial medication.	
4	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence. I will not be identifiable in any results published.	
5	I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by research personnel, responsible individuals from the sponsor and regulatory authorities where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
6	I understand that my GP will be informed of my participation in this trial and sent details of the OPACE trial. My GP may also be informed of any clinical finding from the trial that may require follow up. I will also be informed if this is the case.	
7	I understand that you wish to access my health records held with NHS England and other central UK government bodies that collects outcomes data for linkage, and to do this you will send my NHS number, date of birth and post code to these organisations to link to relevant health data such as, hospital admissions (Hospital Episode Statistics (HES)) and mortality data. Relevant health data for the duration of the trial will be sent to the trial team.	
8	I understand that my personal data might be transferred between the trial team at different trial sites in relation to my participation in this trial. I understand that any personal data will be sent using appropriate secure transfer methods.	
9	I have read and understood the compensation arrangements for this trial as specified in the Participant Information Sheet.	
10	I understand that the doctors in charge of this trial may close the trial, or stop my participation in it at any time without my consent.	

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11	I am happy for disclosure of my identity to the trial coordinating centre for contact (via post, email, or telephone) and follow up purposes for trial.	
12	I am happy for disclosure of my contact details to the trial coordinating pharmacy to arrange home delivery of trial medication.	
13	I understand that de-identified information collected about me may be used to support other research in the future, including research conducted by both commercial and non-commercial organisations in the UK.	
14	If participant or Next of Kin contact is lost, then telephone, text, email or post methods may be used to contact.	

The following is OPTIONAL and is not required for OPACE trial participation. If you agree with the sentence below, please initial each box. If the initials box is left blank/not initialled we will consider this to mean you have declined consent for this specific statement		**INITIALS**
15	I agree to participate in the participant experience feedback survey and be contacted by the OPACE trial coordinating centre for this.	
16	I agree to participate in the participant experience feedback telephone interview and be contacted by the OPACE trial coordinating centre for this.	
17	Please can we contact you about any sub-studies to this OPACE trial.	
18	I agree to be approached to take part in future studies that may not be directly related to the OPACE trial, as outlined in the information sheet.	

I agree to participate in this trial:

_____	_____	_____
Full Name of participant (First name, Surname)	Date	Signature

As consent is taken remotely, only the participant will sign the consent form. The person taking consent will fill in a Confirmation of Consent Form.

For the participant: Please put your initials in this box below as this consent form is completed remotely (for example via a telephone consultation):

INITIALS

Time of Consent (24hr clock) _____:_____

1 copy for the participant, 1 copy for the trial team, 1 copy for the patient's medical notes.

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Principal Investigator: [Printed name to be inserted]
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2	I understand that my participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected, and that any data and samples already collected or tests already performed will continue to be used in the trial as described in this information sheet.	
3	I understand that by participating in this trial, I will need to stop my standard azithromycin or similar long term antibiotic and take trial medication instead. However, I can restart my standard azithromycin or similar long-term antibiotic if I stop taking trial medication.	
4	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence. I will not be identifiable in any results published.	
5	I understand that sections of my medical notes or information related directly to my participation in this trial may be looked at by research personnel, responsible individuals from the sponsor and regulatory authorities where it is relevant to my taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
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