

## **ESCAPE Site Communication Guide**

### **Background to this guide**

We have worked with our patient partners to develop this communication guide for the ESCAPE trial. Its purpose is to assist the research team in explaining the trial to potential participants.

We believe it is important to have clear and consistent communication across all trial sites, to explain why clinical trials are necessary and what this trial aims to achieve.

From our patient partner workshop, we learned that being told you have *Pseudomonas* can be a frightening experience. Many patients do not understand what *Pseudomonas* is or how this may affect their bronchiectasis. Therefore, discussions about joining a trial and treatment options should be approached sensitively.

It is important that patients understand the purpose of the trial and what participation involves before deciding whether to take part.

### **Key topics to cover with participants:**

#### **Why are we doing this trial?**

You have a condition called bronchiectasis and your sputum results show that you have a bacteria called *Pseudomonas aeruginosa* in the lungs.

We are inviting people who have bronchiectasis and a recent colonisation of *Pseudomonas* to take part in this trial.

Having a *Pseudomonas* colonisation means that there are bacteria in your lungs.

This particular bacterium is difficult to treat with many antibiotics failing to clear the infection.

At the moment, we don't have clear evidence about the best way to treat *Pseudomonas* and there is no consistent treatment approach.

The two most common treatment strategies for a new *Pseudomonas* infection are:

- **No change in treatment (usual care):** this involves continuing usual care and current bronchiectasis treatments. A short course of oral or IV antibiotics may be prescribed if there are symptoms of an exacerbation, to see if this can reduce the infection and improve symptoms. No antibiotics would be given if there are no symptoms of infection.
- **Eradication treatment:** this involves a short course of oral or IV antibiotics followed by a longer course of inhaled antibiotics, to see if this can permanently remove the infection.

We do not yet know which treatment is most effective.

If you choose to take part, your participation will help improve our understanding of how best to treat *Pseudomonas* in bronchiectasis and will benefit other people with the condition in the future.

#### **Explaining the trial design**

The ESCAPE trial will randomly assign people with *Pseudomonas* infection to receive one of two treatment strategies.

This means that you will not be able to choose which treatment you receive, but you will be told which treatment you have been allocated to.

We do not know if you will be prescribed any antibiotics or which antibiotics you could be given; this will be decided by the trial doctor after you have been randomised.

We don't know which treatment will work the best.

The purpose of this trial is to compare the two different treatment strategies to find out whether one is more effective than the other in treating *Pseudomonas*.

Running a large clinical trial like this is the only way to collect reliable evidence and guide future treatment for people with bronchiectasis.

### **Treatment options**

The background therapy may involve a short course of oral or IV antibiotics, if there are signs the *Pseudomonas* infection is causing symptoms. If there are no signs and symptoms associated with the infection, then antibiotics may not be required. This will be decided by the trial doctor.

The eradication treatment will involve a 2 week course of oral and/or IV antibiotics, followed by a 3-month course of inhaled antibiotics.

If you are prescribed antibiotics as part of the trial, the specific antibiotics will be chosen and prescribed by the trial doctor.

When the trial treatment has been completed, you will return to your usual treatment.

### **What will happen if you choose to take part**

A computer system will decide randomly which of the two treatments you will receive a bit like flipping a coin.

We will monitor your health and bronchiectasis over two years. This will involve attending some trial visits.

It is important that we monitor you for the full two-year period, to find out whether one treatment strategy is better at controlling or clearing the *Pseudomonas* infection in the long term.

The main things we will monitor are:

- Bronchiectasis exacerbations
- *Pseudomonas* infection in your sputum
- Quality of life & bronchiectasis symptoms (through the trial questionnaires & symptom diary)

No treatments will be withheld from your usual care.

### **What will happen if you choose not to take part**

If you decide not to take part in the trial, there will be no negative consequences for your current treatment.

You will continue to receive normal care from your doctor, and none of your usual treatments will be withheld.

## **Common questions participants may have**

### **Should everyone receive inhaled antibiotics?**

Some guidelines recommend long term inhaled antibiotics for a new *Pseudomonas* infection but this is based on very little evidence.

We do not know whether inhaled antibiotics are effective in eradicating *Pseudomonas*, i.e. completely clear the lungs of the bacterium. This is something we hope to find out from this clinical trial. We think that eradication efforts should be carried out early after the initial diagnosis of *Pseudomonas* but don't have good evidence to support it. That is why a key inclusion criterion for this trial is a recent diagnosis with *Pseudomonas*.

We need more information on whether this treatment can clear the infection in the long term and reduce symptoms.

### **Why do we need to randomise? Why can't patients choose which treatment to receive?**

At the moment, there is no advantage for either treatment approach and we do not know which treatment would be best for you.

The reason we need to randomise is to fairly compare the two treatment strategies and generate reliable evidence about which one is more effective.

By taking part, you will be helping us to determine which treatment has better outcomes. We hope this trial will identify which of the two treatment options will work better in the future for people with bronchiectasis who become newly infected by *Pseudomonas*.

### **Can I receive the inhaled antibiotics without being part of the trial?**

Inhaled antibiotics are not always prescribed for new *Pseudomonas* infection in bronchiectasis, as it is not known whether this treatment can clear the infection in the long term.

You might receive inhaled antibiotics as part of your usual care but this will depend on your local hospital's guidelines, your bronchiectasis symptoms, and which treatment your doctor thinks might benefit you.

### **What if I require inhaled antibiotics during the trial treatment?**

If you are allocated to receive no trial treatment (usual care), you will not be given inhaled antibiotics as part of the trial. However, if your doctor thinks that you require inhaled antibiotics during the trial treatment period, this will not be withheld. Your doctor will provide them if necessary for your care.