Do you have regular COPD flare-ups?

We are looking for people with chronic obstructive pulmonary disease (COPD) who need to improve their disease control further. The information in this pamphlet may help you decide whether you or someone you know may want to take part in this clinical study.

Study code: D3251C00014 Version no.: 1.0 Date: 03–11–2021 UK-enUK

What is a clinical study?

A clinical study is a type of research used to help doctors and researchers confirm if a medicine is safe and works well for a particular medical condition. It offers researchers the chance to explore whether a treatment has side effects and works better than the standard choice of care. The results from these studies can provide opportunities to find better treatments for others in the future.

Taking part is entirely voluntary. Participants may leave the study at any time and for any reason after discussing with their study doctor.

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What is the RESOLUTE study?

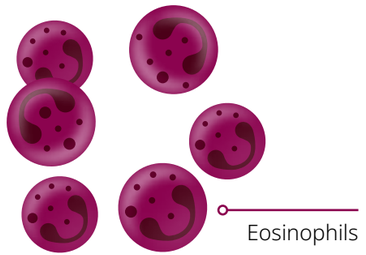
RESOLUTE is a clinical study in patients with COPD with a history of flare-ups (where symptoms are much worse than usual), sometimes called exacerbations, and high levels of eosinophils, a type of white blood cell. The study will see if a medicine called benralizumab brings any benefit to these COPD patients in addition to their inhaler medication.

Optional sub-study

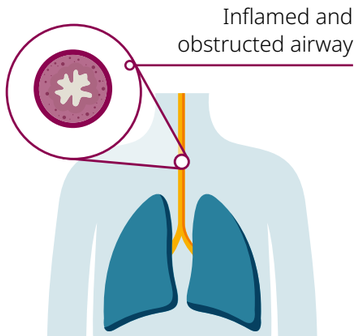
A small group of patients participating in the RESOLUTE study may be able to participate in an extra sub-study. It aims to understand more about how benralizumab works in your lungs.

If you take part in the main study, you do not have to participate in the sub-study. However, your doctor will give you more information if you are interested in taking part.

What is eosinophilic COPD?



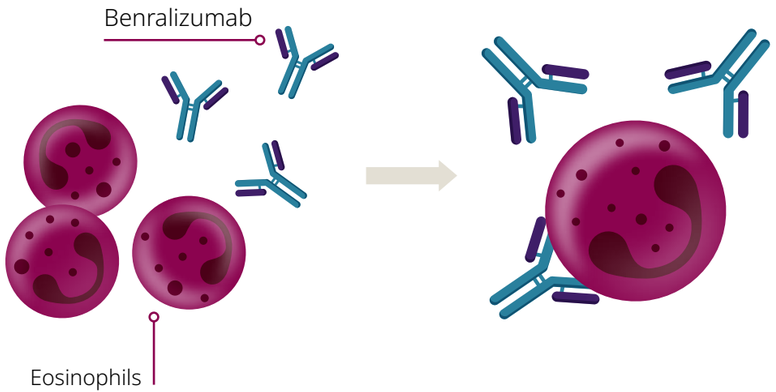
Eosinophils are a type of white blood cell involved in inflammation (or swelling), a part of the body's immune response to injury or infection.

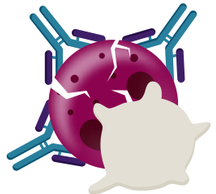


In COPD, high levels of eosinophils can lead to lung inflammation and obstructed airflow, which worsen COPD symptoms.

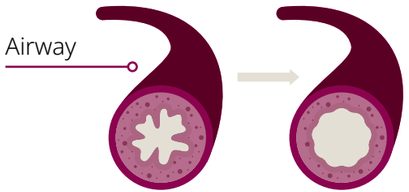
What is benralizumab?

Benralizumab is a protein that lowers the number of eosinophils in the blood.





1 Benralizumab binds to the eosinophils and attracts specific cells in the immune system to remove them from the body naturally.



2 This may help decrease inflammation in the lungs of patients with COPD and reduce their risk of flare-ups.

Two previous studies have shown that benralizumab may reduce flare-ups in patients with COPD and high eosinophil levels in their blood. The purpose of this study is to confirm whether benralizumab can help control COPD symptoms in these patients, in addition to their usual inhaled medications.

Who can join the study?

You may be eligible to join the RESOLUTE clinical study if you:

- Are aged 40–85 years
- Have been diagnosed with advanced COPD based on a spirometry test*
- Have experienced 2 or more flare-ups in the past year that required treatment
- Are a current or ex-smoker who has smoked 20 cigarettes a day for at least 1 year
- Have used triple combination inhaler therapy, which includes inhaled corticosteroids (ICS), long-acting beta-agonists (LABA), and long-acting muscarinic antagonists (LAMA) for the previous 3 months or more

AND

- Have used at least double inhaled therapy of ICS and either LABA or LAMA for the previous year

*Your study doctor will be able to explain this to you in more detail.

What is involved in the study?

The RESOLUTE study has three phases:

Screening period

During screening, your doctor will confirm if you are suitable to participate in the study. It will involve at least two appointments for tests and assessments over a period of **up to 13 weeks**.

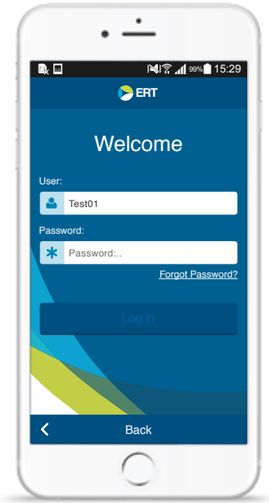
Screening appointments

These screening appointments will involve:

- Taking your medical history
- A physical examination
- Taking your vital signs and measurements (e.g. body temperature, blood pressure, pulse rate, weight, height)
- Lung function tests
- Blood and urine tests
- Chest computed tomography (CT) scan or X-ray
- An electrocardiogram (ECG) test

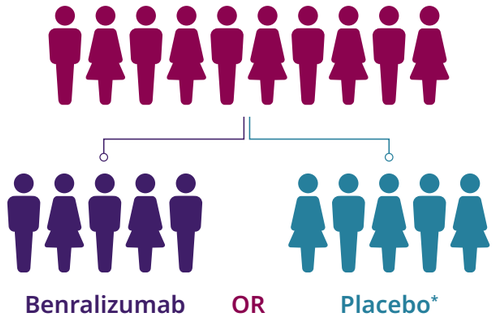
eDiary device

After your first appointment, you will receive an **eDiary device**. The eDiary will contain questions about your COPD symptoms and your daily medication. Answering eDiary questions will take about 15–45 minutes and will need to be completed **every day** for the first year of the study.



Treatment period

If you meet the eligibility criteria, you will move into the treatment phase. The patients who participate in the treatment phase will be split into two groups which receive injections under the skin of either:



Both groups will be the same size, which means you will have a **1 in 2 chance** of receiving the study treatment. The group you are in will be decided at **random** by a computer. Neither you nor your doctor will know what group you are in.

*A placebo is a harmless, dummy treatment that looks like benralizumab and is given the same way but does not contain any active treatment.

During the treatment period, you will:

- Need to attend the study clinic **every 4 weeks** for the first two appointments and **every 8 weeks** thereafter to receive the study treatment or placebo. During these visits you will be asked to have some tests and assessments to monitor your health
  - From your 17th visit, you and/or your caregiver may have the option to be trained to administer the injection at home. For more information, please speak to the study doctor
- Continue using your usual COPD inhaled medications
- Need to complete your eDiary every day

As with all medicines, some side effects might be associated with the treatment you receive during this study. Therefore, it is your responsibility to report any new or worsening symptoms to your study doctor as soon as possible. Your eDiary will send an alert to inform your study doctor immediately in case your responses to the eDiary questions suggest worsening of your health condition.

Due to unexpected circumstances leading to study disruption (for example, public health crises, civil crises, or natural disasters), you may not be able to or may not want to go to the hospital/clinic for study visits. Alternative options for certain study visits may therefore be made available to you.

Optional sub-study

If you participate in the optional sub-study, you will have to visit the study clinic more often and complete some additional tests and assessments during the treatment period.

For more information, please speak to the study doctor.

Follow-up

When your study treatment is stopped, for any reason, you will be asked to attend a follow-up appointment.

Follow-up appointments are critical because they allow the study doctor to monitor the medicine's safety and keep an eye on your health.

Notes

Notes

If you have any questions or would like any more information about RESOLUTE, please speak to the study doctor:

Name:

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Phone:

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Email address:

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The findings from this study will help future patients with COPD.

RESOLUTE STUDY