

Does it cost anything to participate?

There is no cost to participate (except for the participant's usual maintenance triple therapy and rescue medication). Qualified participants receive their assigned add-on study treatment as well as all required study-related medical assessments and examinations at no cost. Compensation for travel expenses incurred as a result of study participation may also be available to those who satisfy applicable requirements.

Are there any risks to participating in the PILLAR Study?

There may be potential risks to participating in this research study. All drugs and medical procedures carry a risk of side effects; therefore, it is possible that participants may experience some discomfort or other reactions from their assigned study treatment. More information on the risks and potential side effects will be explained at the pre-screening visit.

What are the potential benefits of participating?

If you decide you want to participate and are found suitable to participate, it means that your COPD is not ideally controlled on your current medication and the study medication assigned may improve your symptoms. However, it is important to remember that, as with any treatment, one can never be sure of the outcome. If you participate, your health may improve, it may stay the same, or it may get worse. The information learned from this study may help find new treatment options for people suffering from COPD in the future.

What are the next steps?

If you think participating in the PILLAR Study may be right for you, please talk with your family and your doctor. If you wish to take the next step toward possible participation, or if you have more questions, please contact us as directed on the back of this brochure. Contacting us does not obligate you to participate in this research study. Participation is entirely voluntary, and you may withdraw your consent at any time for any reason.

PILLAR



For more information about
the PILLAR Study, please contact:

<CLINIC CONTACT INFO LISTED>

Have you had a
COPD EXACERBATION
IN THE LAST 12 MONTHS
while being treated with an
INHALED MAINTENANCE
TRIPLE THERAPY?



If so, you may qualify to participate in
the PILLAR Study, a research study investigating
whether a new investigational add-on medication
will reduce airway inflammation and **improve COPD**
symptoms in people on maintenance triple therapy.

PILLAR



The World Health Organization estimates that 65 million people worldwide have moderate to severe COPD. COPD is a major cause of disability and is expected to become the leading cause of death globally within the next two decades.

There is no cure for COPD. There are treatments available for doctors to prescribe, including treatments called maintenance therapies to help maintain regular breathing. Common maintenance therapies include types of drugs referred to as long-acting muscarinic antagonists (LAMAs), long-acting beta-2 agonists (LABAs), and inhaled corticosteroids (ICSs). Doctors may prescribe one of these types of drugs or may prescribe a combination therapy of 2 or all 3.

However, even with the combination of all 3 therapies (called “triple therapy”), some people still have COPD symptoms or experience COPD exacerbations, which can result in a hospital admission. The PILLAR Study will assess whether a medication (new investigational or marketed) can reduce the occurrence of these COPD exacerbations when taken in addition to maintenance triple therapy as an “add-on medication.”

The PILLAR Study is only for people who have been prescribed maintenance triple therapy for the last 12 months or longer. If you are unsure whether you satisfy this requirement, please contact us and we will happily discuss it with you.

What medication is being researched in the PILLAR Study?

The medication being researched (called the “Study Drug” in this brochure) is an inhaled medication that may reduce inflammation in the airways. The Study Drug will be dispensed by an inhaler called NEXThaler®. It is expected that delivering the Study Drug directly to the lungs will limit body-wide exposure and reduce unwanted side effects.

What will be researched in the PILLAR Study?

All participants in the PILLAR Study will continue their maintenance triple therapy and take, on top of that, one of four add-on treatments as follows:

- the Study Drug at the higher dose, plus a placebo to be taken orally
- the Study Drug at the lower dose, plus a placebo to be taken orally
- the marketed drug called Roflumilast, to be taken orally, plus a placebo inhaler
- a placebo to be taken orally and a placebo inhaler

A placebo is a substance that looks like the Study Drug but has no active medication.

The PILLAR Study will compare the COPD symptoms experienced by the participants receiving the four different treatments.

The treatment assignment is made randomly by computer. Participants have an equal chance of being assigned to receive each of the treatments.

Who can participate in the PILLAR Study?

To join this study, potential study participants must satisfy the following requirements:

- Be at least 40 years of age
- Have COPD and chronic bronchitis with current symptoms
- Be a current or former smoker who quit 6 or more months before entering the study
- Have had a COPD exacerbation in the past 12 months that either:
 - required hospitalization, OR
 - required oral/injected corticosteroids and/or antibiotics
- Be on inhaled maintenance triple therapy for their COPD for at least 12 months

There are additional requirements to participate. The staff at the study center will explain the complete list of requirements. At a pre-screening and screening visit, the study doctor and his staff will determine whether all requirements to participate are satisfied.

The PILLAR Study will involve approximately 3,980 patients, worldwide.

What will happen during the PILLAR Study?

Participation in the PILLAR Study will last about 56 weeks and will involve 8 visits to the study center. The study is divided into 4 parts:

Pre-screening period

At a pre-screening visit, the study staff will first give a detailed explanation of this study and its potential risks and benefits. This explanation will be made verbally and in writing. Only after obtaining written informed consent from the potential participant will study-specific procedures take place. Study staff will give instructions regarding medications that should not be taken before the next visit, as well as fasting requirements.

Screening period

Next, during a screening visit, the study doctor and the staff will conduct a series of examinations to determine whether the potential participant will pass screening by satisfying all study requirements. Those participants who pass screening will begin a two-week run-in period before the treatment part of the study begins. Participants will be given an electronic diary to record any COPD medications they take and their respiratory symptoms. Participants are expected to record their medications and symptoms daily during the run-in period and also throughout the study.

Treatment period

Participants who continue to qualify after the run-in period will then be assigned to their treatment group and the appropriate treatment will be dispensed. Participants will take the Study Drug by inhalation, plus their daily oral tablet, along with their current maintenance triple medication. Two weeks into the treatment period, study staff will call the participant to check on their status. In addition, there will be 6 visits to the study center during the treatment period, during which various examinations and assessments will be done to monitor the participant's condition.

Follow-up period

Finally, one week after the last study center visit, there will be a telephone follow-up call.

Safety is our top priority. The study doctor may schedule additional visits, if necessary, to check the health status of any participant.