

Thank you for your interest in the PROSERA Study

You may make a difference in the treatment of adults with Pulmonary Arterial Hypertension (PAH)

PROSERA STUDY



What is the PROSERA Study?

The **PROSERA Study** is a Phase 3 clinical research study designed to help researchers understand whether an inhaled investigational product called seralutinib* may be an **effective and safe** future treatment for **adults with pulmonary arterial hypertension**.

Before you decide to join, it is important that you understand why the research is being done and what is involved.



Study Overview

350 adults aged between **18-75 years** with a **diagnosis of PAH**

After a 4-week screening period, to assess your eligibility to participate, the study will last **up to 48 weeks**, with a **follow-up visit 4 weeks** after your final dose (**10-15 visits in total**)

Participants will be **randomised** to receive either **seralutinib inhaled twice daily**, or **placebo**, which contains no active medicine, **inhaled twice daily**

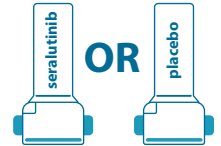
Everyone who completes the study will be invited to continue/switch to seralutinib in the **extension study**



Taking your study drug

Participants in the study will be **randomised** to receive either seralutinib or a placebo. Neither you nor the study doctor will know which study drug you will be getting.

Both the study drug and placebo are administered **using an inhaler**. You will be provided guidance and training on how to take your dose effectively.



What's involved?

Potential participants must first undergo a **screening process** to determine if they are eligible to join the study.

At all stages of the study, you will undergo some tests and procedures. These will indicate to the study staff **how your health is** and **track your progress** through the trial, and may include the following:



Medical history and physical examination



6-minute walk tests (6MWT) – You will be asked to walk as far as you can in six minutes



Blood and urine tests



Lung function test – You will be asked to take deep breaths and blow into a machine to measure how well your lungs are working



Echo- and Electrocardiograms – Tests that provide images of your heart and check its rate and rhythm



Right heart catheterisation (RHC) – A procedure performed to measure the blood pressure inside your lungs and the blood flow and function in the right side of your heart. RHC will be required at screening, **unless** you have had one within the last 6 months

You will be asked to complete **at least two 6MWT** during screening for this study. The 6MWT will be **repeated throughout the study** to evaluate for any changes or potential impact of the study drug that have taken place during the study.



The study drug, device, tests/procedures, and travel expenses will be provided to you at no cost.

At the end of the study, the study results will be made available to you.

For more details on the informed consent process and further information about the PROSERA Study, please contact your doctor or usual healthcare provider.

Clinical Trials Number:
NCT05934526

*Seralutinib has not been approved for commercial use by the US FDA or any other regulatory agency.