

Who can join?

- People 40 years or older diagnosed with IPF within the past 7 years
- Treated with a stable dose of nintedanib (Ofev) or not currently receiving licensed IPF treatment
- Meets other trial requirements explained by the study doctor during screening period

Why join?

Joining a clinical trial is an important, personal decision and there are many reasons to consider joining.

- The possibility of receiving a new, potentially beneficial, treatment in a clinical trial before it is widely available
- Regular medical evaluations and close monitoring by study doctors and nurses
- Learn more about your disease and help researchers learn more about IPF, where treatment options are limited

Learn More

Talk to your doctor to find out if the ASPIRE IPF trial is an option for you. The trial is taking place at locations across the country. If you don't live close to a trial site, some travel-related costs may be reimbursed.

 **Visit:** www.aspire-ipf.com  **Email:** info@aspire-ipf.com

Visit ClinicalTrials.gov and search for NCT06588686

Commitment to your care

Our ambition is to ensure that your experience during the trial is as comfortable and informative as possible. Your participation is invaluable in advancing the understanding of treatment for IPF and potentially improving care for many patients.

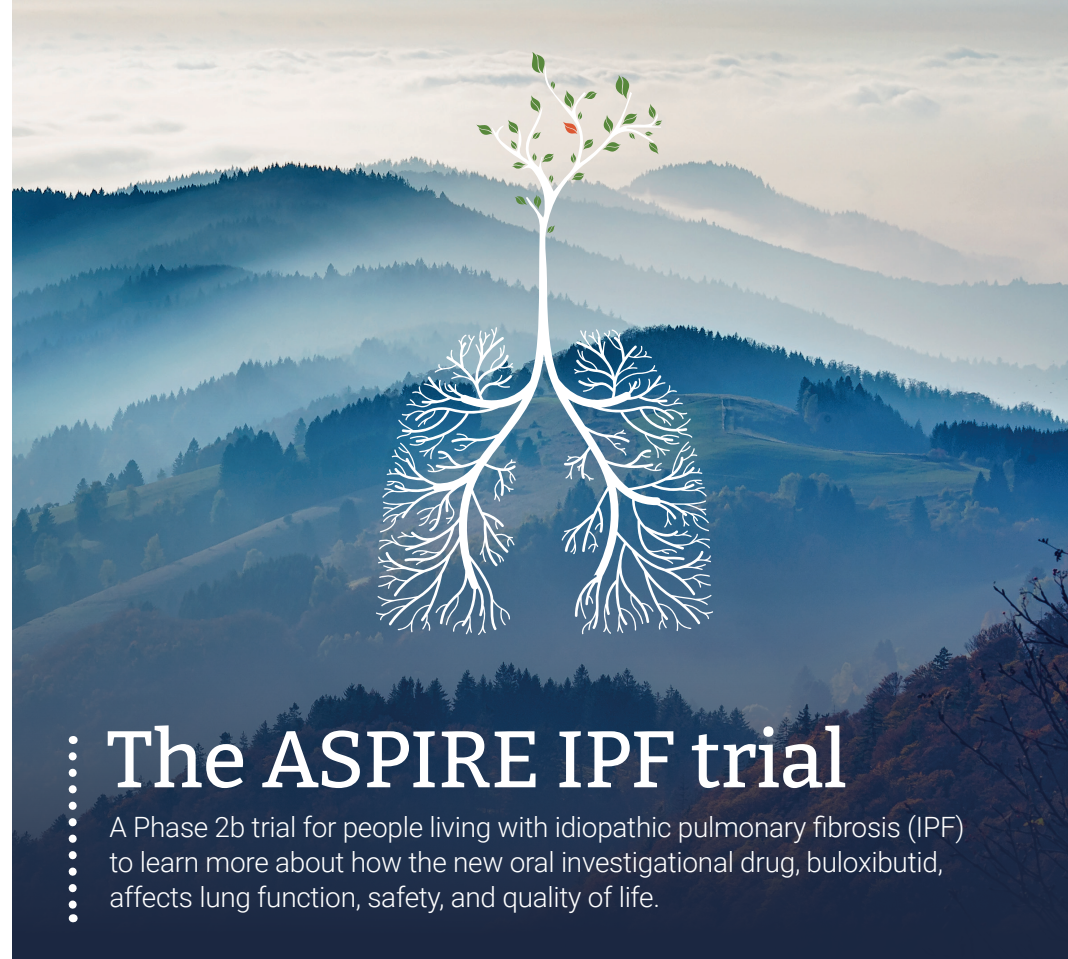


This leaflet is intended for information purposes only and should not replace medical advice. Always consult with your healthcare provider before making decisions about trial participation. Version 3.0 May 2025 | IRB Approved at Protocol Level



Trial sponsor

Vicore is a clinical-stage pharmaceutical company unlocking the potential of a new class of drugs with disease-modifying potential. (www.vicorepharma.com)
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The ASPIRE IPF trial

A Phase 2b trial for people living with idiopathic pulmonary fibrosis (IPF) to learn more about how the new oral investigational drug, buloxibutid, affects lung function, safety, and quality of life.

Now recruiting

ASPIRE IPF is a late-stage Phase 2b clinical trial to further evaluate the efficacy, safety and best dosages of buloxibutid in patients with idiopathic pulmonary fibrosis (IPF). The trial will evaluate the impact of the trial drug on patients' ability to breathe, along with other important measures like safety and quality of life. Two different doses of the trial drug will be compared to placebo over a treatment period of one year.

Buloxibutid is a new oral medicine, designed to activate a natural repair system to reduce and resolve scar formation (fibrosis) in the lungs of people with IPF. As an investigational drug it is not yet approved by any health authority. The ASPIRE IPF trial follows earlier clinical trials in healthy volunteers as well as patients with IPF, including the Phase 2a AIR trial where buloxibutid was given for a 36-week period. Your doctor may inform you about the reported results.

What to expect

The ASPIRE IPF trial involves three stages: a screening period, a treatment period, and a follow-up after the last dose. As a participant in the ASPIRE IPF trial, your involvement will include a series of eight scheduled visits to the clinic complemented with eight regular phone or video calls. This approach ensures close monitoring of your health and wellbeing as well as the efficacy and safety of the investigational drug throughout the trial period. The phone or video calls offer some flexibility and will be scheduled to complement the in-person clinic visits.



Oral buloxibutid or placebo twice daily

- 2/3 of the participants receive trial drug (50 mg or 100 mg)
- 1/3 receive placebo



Participation includes

- Trial examinations, tests and treatments
- Reasonable travel and meal expenses related to clinic visits
- No cost to patients



Appointments with trial team

- 8 in-person visits to the clinic for examinations, tests and questionnaires
- 8 phone or video calls with trial team to monitor your health and wellbeing

Screening

Treatment (52 weeks)

Follow-up

Up to
6
weeks

Day
1

Week
4

Week
12

Week
24

Week
36

Week
52

2-4
weeks

8 in-person visits to clinic

Frequently Asked Questions

How will I know if the treatment is working for me?

You will undergo regular health evaluations, including lung function tests and quality of life assessments among other examinations and tests to assess the effectiveness and safety of the trial drug. Once the trial is completed and analyses of assessments, examinations and tests have been done for all patients in the trial, the results will be made available to you as a participant.

Can I continue with current medicines?

Patients treated with a stable dose of nintedanib (Ofev) are able to join this trial and continue on treatment. Buloxibutid may affect blood levels of other drugs and therefore patients treated with certain medications (for example pirfenidone, also known as Esbriet) cannot participate in this trial. Your doctor will review your current medication list for further guidance.

Is there any cost to participate?

You will receive the trial drug (or placebo) as well as trial related examinations and tests at no cost. You will be reimbursed for reasonable

travel and meal expenses related to attending the trial site clinic visits.

Are there any risks with participating?

Regardless of treatment group, your IPF symptoms or condition may not improve or get worse during the trial period. As with any investigational drug, side effects, including those not yet known, may occur. Your safety will be continuously monitored throughout the trial.

What if I no longer want to participate?

You are free to withdraw from the trial at any time without any impact on your future medical care. Your doctor will

continue to provide care and can advise you about alternative options. If you choose to withdraw, your trial doctor will ask you to attend all the remaining trial visits. However, it is not mandatory that you participate in these visits.

How will my privacy be protected?

Your personal and health information will be kept confidential and secure, in accordance with privacy laws. Data collected will be used for research purposes only, and identifying details will be removed in any shared or published results.

For more questions and answers, see www.aspire-ipf.com 