

1 WHAT WAS THE STUDY AND WHY WAS IT DONE?



Idiopathic pulmonary fibrosis (IPF) is a rare disease that affects the lungs and worsens over time. The tissue around and between the air sacs in the lungs becomes scarred and thickened, making it increasingly more difficult to breathe.

There are 2 approved medicines for IPF, pirfenidone and nintedanib, but they do not stop IPF from continuing to get worse and do not improve the symptoms of people with this disease.

The phase 2 **INTEGRIS-IPF** study wanted to discover if people with IPF who took

bexotegrast or **placebo**

had side effects and if their lung function related to their IPF improved.

2 WHAT MEDICINES WERE USED IN THIS STUDY?

Bexotegrast is a potential new medicine that is being evaluated in people with IPF. It is not yet approved.



Bexotegrast works to stop two receptors ($\alpha_v\beta_6$ and $\alpha_v\beta_1$) that are found at higher levels in a diseased lung and contribute to IPF progression.

\rightarrow These receptors can release a protein called TGF- β , which promotes thickening and scarring of the lungs.



Bexotegrast is taken by mouth once a day.

Placebo is a treatment which looks like the medicine but has no medical effect.



Placebo is taken by mouth once a day.

3 WHO TOOK PART IN THIS STUDY?

This was a double-blind, randomized study, which means that each person was put into 1 of 2 treatment groups by chance, and neither the people who took the medicine nor the researchers knew which treatment (**bexotegrast** or **placebo**) was being given.



119 adults with IPF were included in this study.



39 sites across North America, Europe, Australia, and New Zealand participated in this study.

88

were given **bexotegrast** every day for at least 12 weeks.

31

were given **placebo** every day for at least 12 weeks.

About **80%** of people were also **taking either pirfenidone or nintedanib**.

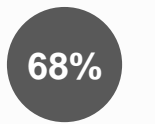


4 WHAT WERE THE MAIN FINDINGS OF THIS STUDY?

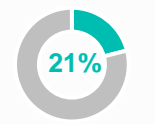
How many adults had side effects?



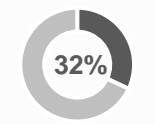
Bexotegrast
Had side effects during the study for any reason.



Placebo
Had side effects during the study for any reason.



Bexotegrast
Had side effects that were related to the study medicine.



Placebo
Had side effects that were related to the study medicine.

No one had any serious side effects (death, hospitalization) related to the medicine during the study.



Using **bexotegrast** alone or with pirfenidone or nintedanib was well tolerated.

How well did the treatment work?



People taking **bexotegrast** had a slower decline in lung function compared with people who took **placebo**.



Bexotegrast was well tolerated in patients with IPF and may slow the decline of lung function. Additional studies are evaluating this further.