A study in patients with idiopathic pulmonary fibrosis (IPF) to better understand how nintedanib slows disease progression (1199.227)

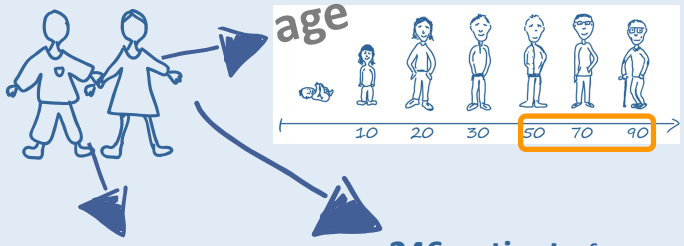
Boehringer Ingelheim

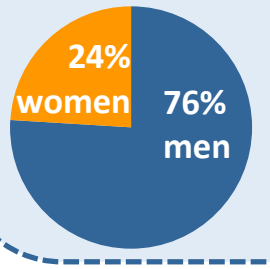
IPF is a disease that causes **scarring in the lungs**. This makes it difficult to breathe. **Nintedanib** is a medicine that can **slow down the progression** of IPF.

This **study** was to find out:

How does **nintedanib** influence the amount of a protein called **CRPM** in the blood?

Study participants had IPF





346 patients from **13 countries** from Europe, Asia, Australia and North America took part.

This study had 2 parts:

Part 1 → 1 week 1-12

Part 2 → 2 week 13-52

Each participant took twice a day

Part 1

1 150 mg nintedanib

or

1 placebo which didn't contain any medicine

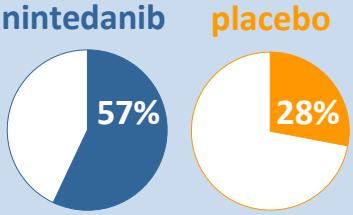
Part 2

1 150 mg nintedanib

After 12 weeks all participants took nintedanib.

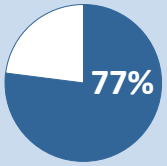
1 Part 1

57% of participants who took nintedanib and 28% of participants who took placebo had **unwanted effects**.



2 Part 2

77% of the participants had **unwanted effects**.



RESULTS

After 12 weeks, the **change in CRPM** was **not different** in participants taking nintedanib and participants taking placebo.

A study in patients with idiopathic pulmonary fibrosis (IPF) to better understand how nintedanib slows disease progression

This is a summary from one clinical study.

We thank all study participants. You helped to answer important questions about nintedanib and the treatment of IPF.

What was this study about?

Idiopathic pulmonary fibrosis (IPF) is a rare disease that causes scarring of the tissue inside the lungs. The lungs become thick and stiff (fibrotic). This makes breathing difficult. The word 'idiopathic' means that doctors do not know the cause of the lung scarring. Common symptoms of IPF are shortness of breath, persistent dry cough, and enlargement (clubbing) of fingertips. Nintedanib is a medicine that is used to slow down the progression of IPF.

The purpose of the study was to measure how nintedanib affects a certain protein in the blood called CRPM. CRPM has been shown in other clinical studies to increase as IPF worsens. We expected that if nintedanib had an effect on CRPM, it could provide more information about how nintedanib works.

Who took part in this study?

All participants in this study had IPF.

Overall, 346 participants took part in the study. This included 262 men and 84 women. The average age was 70 years. The youngest participant was 49 years old and the oldest participant was 91 years old.

This study was done in Europe, Asia, Oceania, and North America. The table below shows the countries that the study was done in.

Region	Countries	Number of Participants
Europe	Belgium, Czech Republic, Finland, France, Germany, Hungary, Poland, Spain, United Kingdom	213
Asia	Japan, Korea	102
Oceania	Australia	20
North America	United States	11

How was this study done?

This study had 2 parts. The first part lasted for 12 weeks and the second part lasted for 40 weeks.

In the first part of the study, the participants were divided into 2 groups. It was decided by chance which participants were in each group. The groups were:

- Nintedanib group: participants took 1 tablet of 150 mg nintedanib twice per day
- Placebo group: participants took 1 placebo tablet twice per day

Placebo tablets looked like nintedanib but did not contain any medicine. 116 participants were in the nintedanib group and 230 participants were in the placebo group. The participants and doctors did not know whether the participants were in the nintedanib group or in the placebo group.

We wanted to know if there was a difference in the amount of CRPM in the blood after taking nintedanib for 12 weeks. We compared the amount of CRPM in participants who took nintedanib with the amount of CRPM in participants who took placebo.

In the second part of the study, all participants took 1 tablet of 150 mg nintedanib twice per day for 40 weeks. All participants knew that they were now taking nintedanib. Participants who were taking nintedanib in part 1 continued to take nintedanib. Participants who were taking placebo in part 1 switched to nintedanib in part 2. We wanted to know if there was a difference between treatments. We measured how well the lungs worked at the end of the study compared to the beginning of the study. We also wanted to know if there was a difference in the number of participants who died.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participant's health.

What were the results of this study?

After 12 weeks, the average change in the amount of CRPM in the blood was not different between groups. The groups were participants taking nintedanib compared to participants taking placebo.

By the end of the study, similar percentages of participants in both treatment groups had decreased lung function or had died. 29 out of 116 participants (25%) who took nintedanib throughout the whole study had decreased lung function or had died. 70 out of 230 participants (30%) who took placebo during the first 12 weeks had decreased lung function or had died.

Did participants have any unwanted effects?

Yes, participants in both groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by the study medicines. During the first part of the study, 66 out of 116 participants (57%) in the nintedanib group had unwanted effects. 64 out of 230 participants (28%) in the placebo group had unwanted effects.

The table below shows the 6 most common unwanted effects in either treatment group.

Unwanted effect	**Nintedanib 150 mg twice daily (116 participants)**	**Placebo (230 participants)**
Diarrhoea	47 participants (41%)	34 participants (15%)
Nausea	16 participants (14%)	10 participants (4%)
Decreased appetite	11 participants (10%)	7 participants (3%)
Decreased weight	6 participants (5%)	1 participant (less than 1%)
Vomiting	5 participants (4%)	5 participants (2%)
Abdominal discomfort	5 participants (4%)	1 participant (less than 1%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, or were life-threatening. Unwanted effects were also serious if the doctor thought they were serious for any other reason. During the first part of the study, 1 participant out of 116 participants (less than 1%) in the nintedanib group had serious unwanted effects. 2 participants out of 230 participants (less than 1%) in the placebo group had serious unwanted effects.

All participants took nintedanib during the second part of the study. During this period, 256 participants out of 333 participants (77%) had unwanted effects. The most common unwanted effects were the same as in the first part of the study. 13 participants out of 333 participants (4%) had serious unwanted effects during the second part of the study.

Where can I find more information about this study?

You can find further information about the study at these websites:

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1199.227.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-003148-38.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02788474.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A 12-week, double-blind, randomised, placebo-controlled, parallel-group trial followed by a single active arm phase of 40 weeks evaluating the effect of oral nintedanib 150 mg twice daily on change in biomarkers of extracellular matrix (ECM) turnover in patients with idiopathic pulmonary fibrosis (IPF) and limited forced vital capacity (FVC) impairment'.

This was a Phase 4 study. This study started in June 2016 and finished in June 2018.

Are there additional studies?

If we do more clinical studies with nintedanib, you will find them on the websites listed above. To search for these studies, use the words nintedanib and BIBF 1120.

Important notice

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Usually, more than one study is carried out in order to find out how well a medicine works and the side effects of the medicine. Other studies may have different results.

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.