INBUILD®: A study to find out if a medicine called nintedanib helps people with progressive lung fibrosis (1199.247)

Boehringer Ingelheim

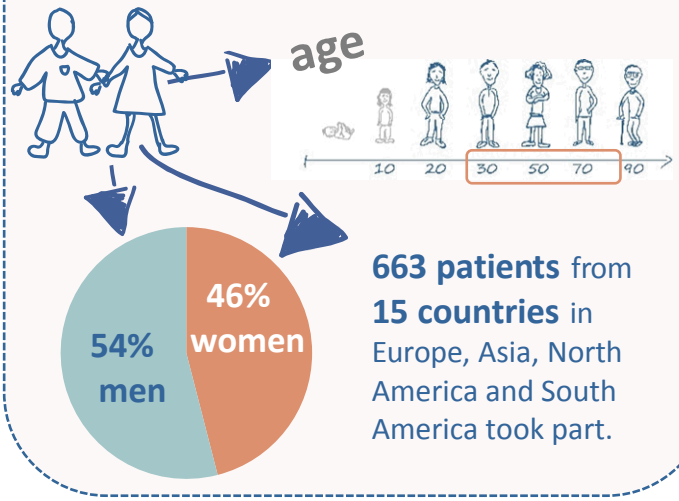
Lung fibrosis causes the lung tissue to become thick, stiff, and scarred. This can make breathing hard. **Progressive** lung fibrosis means that scarring in the lungs gets worse over time.

This **study** wanted to find out:

Does a medicine called **nintedanib** help people with progressive lung fibrosis?

Study participants

had progressive lung fibrosis



663 patients from **15 countries** in Europe, Asia, North America and South America took part.

Each participant took twice a day

1 150 mg nintedanib

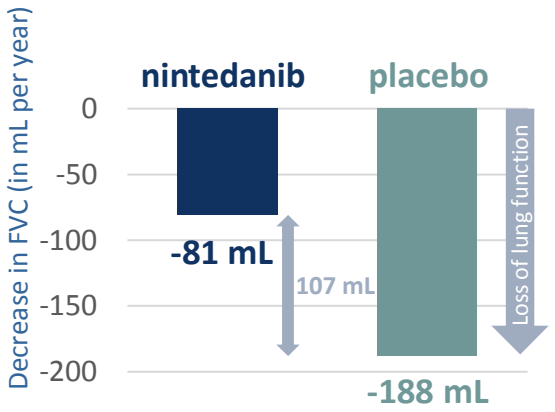
or

1 placebo

which didn't contain any medicine

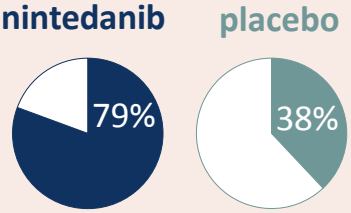
RESULTS

On average, after 1 year, **nintedanib slowed down** the **loss of lung function by 57%**.



The results were similar independent of the pattern of fibrosis seen on chest imaging.

79% of participants who took nintedanib and 38% of participants who took placebo had **unwanted effects**.



Diarrhoea was the most common unwanted effect: 59% of participants taking nintedanib and 18% of participants taking placebo had diarrhoea.

INBUILD®

A study to find out if a medicine called nintedanib helps people with progressive lung fibrosis

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about nintedanib and the treatment of progressive lung fibrosis.

What was this study about?

The purpose of this study was to find out whether a medicine called nintedanib helps people with progressive lung fibrosis. Lung fibrosis causes the lung tissue to become thick, stiff, and scarred. This leads to loss of lung function and can make breathing difficult.

In some people, lung fibrosis is progressive. This means that it worsens over time.

Lung fibrosis can occur in people with interstitial lung diseases, also called ILDs. ILDs affect the tissue and space around the air sacs of the lungs.

Lung fibrosis can occur because of inhalation of a harmful substance. Lung fibrosis can also be associated with diseases like rheumatoid arthritis or sarcoidosis. However, in many people with lung fibrosis, the cause is unknown. Doctors call diseases with an unknown cause 'idiopathic'.

Nintedanib is a medicine used to treat idiopathic pulmonary fibrosis (IPF), which is a type of progressive lung fibrosis. In IPF, nintedanib can help to slow down the worsening of lung function. Researchers think that nintedanib can block biological signals that take place in the process of lung fibrosis. In this study, we wanted to check if nintedanib also works for other types of progressive lung fibrosis.

Who took part in this study?

Adults with various types of progressive lung fibrosis participated in the study. Because we already knew that nintedanib works in people with IPF, patients with this disease could not take part.

663 participants took part in the study. 356 participants were men and 307 participants were women. The average age was 66 years. The youngest participant was 27 years old and the oldest participant was 87 years old.

The following table shows the numbers of participants in the study in different regions.

Region	Countries	Number of Participants
Europe	Belgium, France, Germany, Italy, Poland, Russia, Spain, United Kingdom	301
Asia	China, Japan, South Korea	155
North America	Canada, United States	136
South America	Argentina, Chile	71

How was this study done?

The participants were divided into 2 groups of almost equal size. Every participant had an equal chance of being in each group. The groups were:

- Nintedanib group: participants took 1 capsule of 150 milligrams (mg) nintedanib twice a day
- Placebo group: participants took 1 capsule of placebo twice a day

The placebo capsules looked like the nintedanib capsules, but did not contain any medicine. The participants and doctors did not know who was in the nintedanib group and who was in the placebo group.

If participants had unwanted effects, the doctors could lower the dose to 100 mg twice a day or even stop their treatment for a while.

It was planned that participants stay in the study for at least 1 year. Some participants stayed in the study for longer, until the study was finished. During this time, the participants visited their doctors regularly. At these visits, the doctors collected information on each participant's health.

To see if nintedanib could slow down the loss of lung function, a lung function test was used. The test measured, in millilitres, how much air a participant could exhale into a device. This measurement is called forced vital capacity, or FVC. It indicates the volume of the lungs. We measured how much FVC changed over 1 year. A decrease in FVC over 1 year meant a loss of lung function.

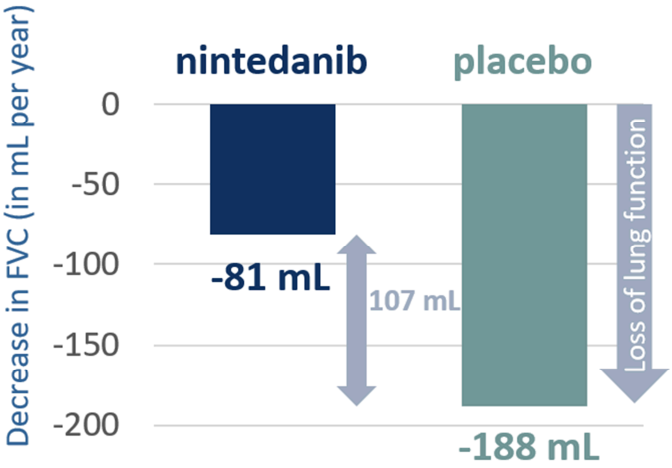
We looked at how much FVC changed in all participants.

We also looked at FVC in groups of participants with different patterns of fibrosis in the lungs. These patterns can be seen with computerised tomography (CT) scans of the chest. CT scans use x-rays to create images of the inside of the body. We wanted to see if the medicine worked the same in people with different patterns of fibrosis in the lungs.

What were the results of this study?

Compared with placebo, nintedanib slowed down the loss of lung function in study participants. Because the participants had progressive lung fibrosis, loss of lung function was expected.

The graph below shows the average yearly loss of lung function in participants who took nintedanib (blue bar on the left) and participants who took placebo (green bar on the right). On average, after 1 year of treatment, nintedanib slowed down the loss of lung function by 57%. The results were similar independent of the pattern of fibrosis seen on chest imaging.



We did statistical tests on the results. These tests showed it was unlikely that the differences between the treatment groups happened by chance.

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 nintedanib or placebo.

During 1 year of treatment, 262 out of 332 participants (79%) in the nintedanib group had unwanted effects. 126 out of 331 participants (38%) in the placebo group had unwanted effects.

The table below shows the most common unwanted effects. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	**Nintedanib** **332 participants were in this group** 	**Placebo** **331 participants were in this group** 
Diarrhoea	196 participants (59%) 	59 participants (18%) 
Nausea	79 participants (24%) 	19 participants (6%) 
Vomiting	41 participants (12%) 	7 participants (2%) 
Decreased appetite	37 participants (11%) 	10 participants (3%) 
Increase in an enzyme that may indicate problems with your liver (alanine aminotransferase increased)	36 participants (11%) 	8 participants (2%) 

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, were life-threatening, or fatal. Unwanted effects were also serious if they led to disability or the doctor thought they were serious for any other reason. During 1 year of treatment, 21 participants (6%) in the nintedanib group had serious unwanted effects. 13 participants (4%) in the placebo group had serious unwanted effects.

No participants in the nintedanib group died from unwanted effects during 1 year of treatment. One participant in the placebo group died from unwanted effects.

Where can I find more information about this study?

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

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number **BI 1199.247.**
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number **2015-003360-37.**
3. Go to www.clinicaltrials.gov and search for the NCT number **NCT02999178.**

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'INBUILD®: A double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of nintedanib over 52 weeks in patients with Progressive Fibrosing Interstitial Lung Disease (PF-ILD)'.

This was a Phase III study. This study started in February 2017 and ended in August 2019.

Are there additional studies?

Participants who completed this study could participate in a follow-up study, INBUILD-ON® (study number: 1199-0248). In the INBUILD-ON® study, all participants receive nintedanib. The INBUILD-ON® study is ongoing.

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

Acknowledgement

We would like to thank the following patient organisations for their advice in the development of this lay summary:

- Action for Pulmonary Fibrosis (APF)
- Asociación de Familiares y Enfermos de Fibrosis Pulmonar Idiopática (AFEFPI)
- Association Française des Polyarthritiques et des Rhumatismes Inflammatoires Chroniques (AFPric)
- Association Nationale de Défense contre l'Arthrite Rhumatoïde (ANDAR)
- Association Pierre Enjalran Fibrose Pulmonaire Idiopathique (APEFPI)
- Canadian Pulmonary Fibrosis Foundation
- Federation of European Scleroderma Associations aisbl (FESCA)
- Hellenic League Against Rheumatism (ELEANA)
- Idiopathic Pulmonary Fibrosis Association Bulgaria
- Irish Lung Fibrosis Association (EU-IPFF secretary)
- Liga Reumatológica Española (LIRE)
- Lungenfibrose e.V
- Pulmonary Fibrosis Foundation
- Scleroderma Canada
- The European Idiopathic Pulmonary Fibrosis and Related Disorder Federation (EU-IPFF)
- The Pulmonary Fibrosis Trust
- Un respiro di speranza

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.