This is a summary of a clinical study in patients with idiopathic pulmonary fibrosis, a rare type of lung disease. It is written for the general reader and uses language that is easy to understand. It includes information about how researchers did the study and what the results were. The simplified title for the study is: 'A study of nintedanib to slow the amount of scarring in the lungs of patients with idiopathic pulmonary fibrosis'.

We thank all patients who took part in this study. Through your participation, you helped researchers answer important questions about nintedanib and the treatment of idiopathic pulmonary fibrosis.

What was this study about?

Patients with idiopathic pulmonary fibrosis (IPF) have scar tissue that accumulates in their lungs. The researchers wanted to know if patients who took a medicine called nintedanib for 6 months had less scar tissue than patients who took placebo for 6 months. To test this, the researchers took special scans called high-resolution computed tomography, or HRCT, of each patient's chest. The scans were done at the beginning of the study and again after 6 months of treatment. Researchers also collected information on the unwanted effects of nintedanib.

This study started in December 2013 and finished in October 2016. This study was stopped early because nintedanib and another medicine received approval for the treatment of IPF. Because of this, fewer patients entered the study than were planned. The sponsor of this study was Boehringer Ingelheim.

Why was the study needed?

This study examined if nintedanib slowed down the scarring in the lungs. Idiopathic pulmonary fibrosis is a rare disease that causes scarring of the tissue inside the lungs. The scarring makes the lungs become thick and stiff (fibrotic). This makes breathing difficult. The word 'idiopathic' means that doctors do not know the cause of the disease.

Which medicines were studied?

Researchers studied a medicine called nintedanib (also known as BIBF 1120). Nintedanib received approval during this study as a medicine used to treat patients with IPF. Nintedanib is given as a capsule taken by mouth.

Some patients in the study were treated with nintedanib, and the others were treated with a placebo. The placebo capsules looked just like the nintedanib capsules, but did not contain any medicine.

Who participated in the study?

Patients who had been diagnosed with IPF within the last 5 years could take part in this study. Patients also had to be at least 40 years old.

Originally, researchers planned for 275 patients to take part. Nintedanib was approved for treating IPF before all planned patients were enrolled. Therefore, only 113 patients took nintedanib or placebo in the study. A total of 82 patients were men and 31 were women. The average age was 68 years. The youngest patient was 45 years old and the oldest patient was 88 years old. On average, patients had been diagnosed with IPF about 1.5 years before the study started. There were 67 patients in Canada, 24 patients in United States, and 22 patients in Turkey.

How was this study done?

The patients were divided into 2 groups. It was decided by chance who got into which group. One group of 56 patients was given nintedanib, and the other group of 57 patients was given placebo. Neither the patients nor the study doctors knew which treatment the patients received.

Patients took nintedanib capsules or placebo capsules twice a day. Patients in the nintedanib group started on a dose of 150 milligrams (mg) twice a day. This dose could be decreased if the patients had unwanted effects that they could not tolerate.

It was planned for patients to be treated with either nintedanib or placebo for 6 months. After this 6-month treatment period, patients in the nintedanib group could continue to take nintedanib. Patients in the placebo group could switch to take nintedanib. Treatment was planned to continue for up to 18 months, but the study was stopped after the last patient had at least 6 months of treatment.

Researchers measured the amount of scar tissue in each patient's lungs and assigned a quantitative lung fibrosis (QLF) score. The QLF score for each patient was recorded at the beginning of the study and again after 6 months of treatment.

What were the results of this study?

Both treatment groups had similar QLF scores at the beginning of the study. After 6 months of treatment, the average QLF score increased in both treatment groups compared with the beginning of the study. Because the study was stopped early, there were not enough patients to reach clear conclusions on the results of this study.

What unwanted effects did patients have?

During the 6-month treatment period, 44 out of 56 patients (79%) in the nintedanib group had unwanted effects. In the placebo group, 33 out of 57 patients (58%) had unwanted effects.

The most common unwanted effects seen in at least 10% of patients in either group are shown in the table below.

Doctors keep track of all health problems patients have during a study. Some of these health problems might be caused by the study medicines, and some by other medicines taken by the patient. Others might be caused by the disease, and some have yet a different cause. Here we describe health problems that the doctors thought were caused by the study medicines. These health problems are called unwanted effects.

	Nintedanib (56 patients)	Placebo (57 patients)
Patients with any unwanted effect	44 patients (79%)	33 patients (58%)
Diarrhoea	38 patients (68%)	21 patients (37%)
Nausea	14 patients (25%)	11 patients (19%)
Decreased appetite	11 patients (20%)	3 patients (5%)
Vomiting	9 patients (16%)	1 patient (2%)
Feeling tired (fatigue)	8 patients (14%)	0 patients
Weight loss	7 patients (13%)	0 patients

Some patients in the study had serious unwanted effects. An unwanted effect was serious if it caused the patient to go to the hospital or stay longer in the hospital. It was also serious if it needed a doctor's immediate attention, was life-threatening, or caused death.

During the 6-month treatment period, a total of 1 out of 56 patients (2%) in the nintedanib group had serious unwanted effects. In the placebo group, 3 out of 57 patients (5%) had serious unwanted effects.

A total of 2 patients out of 56 patients (4%) in the nintedanib group died during the 6-month treatment period. During this period, 4 patients out of 57 patients (7%) in the placebo group died. Of these patients, 1 patient in the nintedanib group and 2 patients in the placebo group died due to unwanted effects. The patient who died in the nintedanib group had inadequate blood flow in the intestine (intestinal infarction). The patients in the placebo group died due to IPF and their lungs not functioning (respiratory failure).

Are there follow-up studies?

No follow-up studies are planned.

Where can I find more information?

You can find the scientific summaries of the study results at these websites:

www.trials.boehringer-ingelheim.com	search for the study number: 1199.187
www.clinicaltrials.gov	search for the NCT number: NCT 01979952

The full title of the study is:

'A six month double-blind, randomized, placebo-controlled trial, followed by each arm being converted to oral nintedanib 150 mg twice daily, comparing the effect on high resolution computerized tomography quantitative lung fibrosis score, lung function, six-minute walk test distance, and St. George's Respiratory Questionnaire after six months of treatment in patients with idiopathic pulmonary fibrosis with continued evaluations over a period of up to eighteen months'.

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.