

---

## A study to look at the effect of nintedanib on birth control medicine in patients with lung cancer

This is a summary of a clinical study of a substance called nintedanib. It is written for the general public. It includes information about how researchers did the study and what happened during the study.

---

We thank the patients who took part in this study.

---



### What was this study about?

Some medicines may affect the amount of hormonal birth control medicine in the blood. This can make the birth control medicine (the pill) less effective. Researchers wanted to find out whether a drug called nintedanib influences the amount of birth control medicine in the blood.

This study started in June 2016 and finished in November 2017. This study was stopped early because fewer patients entered the study than were planned.



### Why was the study needed?

Nintedanib is a medicine that is approved in some countries to treat a type of lung cancer called non-small cell lung cancer (NSCLC). Nintedanib is also approved in more than 60 countries to treat idiopathic pulmonary fibrosis. Women who could get pregnant must use highly effective methods of birth control while taking nintedanib. This is because nintedanib could harm an unborn baby.

Researchers wanted to find out if nintedanib had any influence on how much of the birth control medicine was in patients' blood. They planned to use the results from this study to advise patients about the type of birth control to use.



### Which medicines were studied?

Nintedanib is a medicine that helps to stop cancer from growing and spreading. Nintedanib blocks the development of new blood vessels in growing tumours. It is used to treat a certain type of lung cancer in combination with chemotherapy (docetaxel). Nintedanib is taken as a capsule by mouth.

Ethinylestradiol and levonorgestrel are components of a commonly used birth control medicine. This birth control medicine is taken as a tablet by mouth.



## Who participated in the study?

The study included women with NSCLC who were planning to start treatment with nintedanib. Overall, 2 patients took part in the study, out of 24 patients planned. The average age was 67.

Both patients were from Germany.



## How was this study done?

Both patients received birth control medicine and nintedanib. The patients and their doctors knew which treatment they were given.

On the first test day, patients took a tablet of the birth control medicine (30 micrograms of ethinylestradiol plus 150 micrograms of levonorgestrel). Blood samples were collected.

Before the second test day, patients had taken 2 tablets of nintedanib (200 milligrams) each day for at least a week. On the second test day, patients took another tablet of birth control medicine together with nintedanib. Blood samples were collected.

Researchers checked how much birth control medicine was in patients' blood on test days 1 and 2.

Patients visited their doctors regularly. During the visits, the doctors collected information on each patient's health.




## What were the results of this study?

The study was stopped early. There were not enough patients to reach clear conclusions about the results of the study.



## Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 1 out of 2 patients had an unwanted effect of diarrhoea. 1 out of 2 patients had an unwanted effect of pain in arms or legs (extremities).



## Are there follow-up studies?

Another study to check if nintedanib has an effect on birth control medicine will be conducted in the future.

If more clinical studies with nintedanib are done, they may be found on the public websites listed below. To search for these studies, use the following names: BIBF 1120, nintedanib.



## Where can I find more information?

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

[www.trials.boehringer-ingelheim.com](http://www.trials.boehringer-ingelheim.com) search for the study number: 1199.238

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) search for the NCT number: NCT02751385

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

‘A Phase I trial to investigate the effect of nintedanib on the pharmacokinetics of a combination of ethinylestradiol and levonorgestrel in patients with non-small cell lung cancer’.

---

## 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.

©Boehringer Ingelheim International GmbH.

---

Icons ©Fotolia by Matthias Enter