

A study to test whether nintedanib influences the components of birth-control pills in women with Systemic Sclerosis associated Interstitial Lung Disease (SSc-ILD)

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about nintedanib.

What was this study about?

The purpose of this study was to find out whether a medicine called nintedanib affects the amount of hormonal birth-control medicine (the pill) in the blood of women. Nintedanib is used to treat different types of lung fibrosis, including systemic sclerosis associated interstitial lung disease (SSc-ILD).

Women who can get pregnant must use highly effective methods of birth control while taking nintedanib. This is because nintedanib could harm an unborn baby. Some medicines may affect the amount of birth-control medicine in the blood. This can make the birth-control medicine less effective.

Who took part in this study?

17 women with SSc-ILD took part in the study. The youngest participant was 30 years old and the oldest participant was 83 years old. The average age was 59 years.

The study took place in Spain, Belgium, Germany, The Netherlands, and Portugal.

How was this study done?

We compared the amount of birth-control medicine in the blood when the participants took it by itself compared with the amount when they took it together with nintedanib.

The participants first took a single dose of birth-control medicine. At least 3 days later, the participants took nintedanib twice daily for 2 to 4 weeks. On one of the days of nintedanib treatment, they also took a single dose of birth-control medicine. Birth-control medicine was taken as a tablet. Nintedanib was taken as a capsule.

The doctors took blood samples at different times during the study. The doctors also collected information about the participants' health.



What were the results of this study?

This study showed that taking nintedanib did not affect the amount of birth-control medicine in the blood.








Did the participants have any unwanted effects?

Yes, participants in this study had unwanted effects. Unwanted effects are any health problems that the doctors think were caused by nintedanib or birth-control medicine. In this study:

- None of the participants had unwanted effects when they took birth-control medicine alone.
- 9 out of 17 participants (53%) had unwanted effects when they took nintedanib or nintedanib plus birth-control medicine.

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 or nintedanib plus birth-control 17 participants	
Diarrhoea	5 participants (29%)	
Vomiting	5 participants (29%)	
Nausea	4 participants (24%)	
Pain in the upper abdomen	3 participants (18%)	

Some unwanted effects are considered serious because the doctor thinks they are serious for any reason. In this study, 1 participant had a serious unwanted effect.

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 1199-0340.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2018-001177-24.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03675581.

Boehringer Ingelheim sponsored this study.

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 female patients with Systemic Sclerosis associated Interstitial Lung Disease (SSc-ILD)'.

This study started in January 2019 and finished in October 2019.

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.

People who took part in this study could participate in a follow-up study with nintedanib, SENSICIS-ON® (study number: 1199-0225).

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.

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