Summary of Clinical Trial Results

A study of sildenafil added on top of pirfenidone compared with placebo added on top of pirfenidone – in people with advanced idiopathic pulmonary fibrosis

See the end of the summary for the full title of the study.

About this summary

This is a summary of the results of a clinical study, written for:

- members of the public; and
- people who took part in the study.

This summary is based on information known at the time of writing. More information may now be known.

The study started in January 2017 and will end in August 2020. This study has two parts. The first part of the study looked at how well sildenafil added on top of pirfenidone worked over 1 year – known as efficacy – and how safe this medicine was. At the end of the first part of the study, people stopped taking sildenafil, but continued to take pirfenidone for another 11 months (second part of the study).

At the time of writing this summary, the second part of the study – which focuses on the safety of long-term treatment with pirfenidone – is still taking place. However, to make the results available to the public as soon as possible, this summary presents the results from the first part of the study. The results from the second part of the study will be available at a later date.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.

Contents of this summary

Layperson summary date: August-2020
Veeva number: M-XX-00001935

Thank you to the people who took part in this study

The people who took part in this study have helped researchers to answer important questions about the study medicine in people with advanced idiopathic pulmonary fibrosis at risk of pulmonary hypertension – meaning they either had pulmonary hypertension or were at risk of getting pulmonary hypertension.

Key information about this study

- About this study:
  - This study was done to find out whether sildenafil could help people with advanced idiopathic pulmonary fibrosis (IPF) who are at risk of pulmonary hypertension.
- About IPF:
  - IPF is a rare lung disease that causes scarring of the lungs.
  - There are two medicines available to treat people with IPF – pirfenidone and nintedanib. These medicines do not cure IPF, but they can slow down scarring of the lungs.
  - Many people with IPF get high blood pressure in the vessels supplying the lungs – known as pulmonary hypertension.
  - There are no approved medicines to prevent or treat pulmonary hypertension in people with IPF.
- This study was done because sildenafil helps people with another type of high blood pressure called pulmonary arterial hypertension.
- This study included 177 people in 13 countries.
- People included in this study:
  - Had advanced IPF.
  - Either had pulmonary hypertension or were at risk of developing pulmonary hypertension.
- Participants were given either sildenafil and pirfenidone or placebo and pirfenidone for 1 year.
  - A placebo looks the same as the medicine being tested in a study, but it does not contain any real medicine. This means that it has no medicine-related effect on the body.
- The main finding was that adding sildenafil to pirfenidone did not show any benefit compared with adding placebo to pirfenidone.
- Few studies have included people with advanced IPF.
  - The safety of pirfenidone in this study was similar compared with previous studies in people with less advanced IPF.
  - This study suggested that people with advanced IPF might benefit from taking pirfenidone.
- Around 2% of people (2 out of 88 people) taking sildenafil + pirfenidone had serious side effects that the study doctor believed were related to the treatments in the study, compared with around 4% of people (4 out of 89 people) taking placebo + pirfenidone.
- At the time of writing this summary, the second part of this study is still happening – the additional safety follow-up. It will end in August 2020.
- However, to make the results available to the public as soon as possible, this summary presents the results from the first part of the study.

1. General information about this study

Why was this study done?

Researchers wanted to learn more about whether sildenafil could help people with advanced idiopathic pulmonary fibrosis (IPF) who are at risk of pulmonary hypertension – meaning they either had pulmonary hypertension or were at risk of getting pulmonary hypertension.

IPF is a rare lung disease where the lungs become scarred – known as fibrosis – and breathing becomes increasingly difficult. The cause of IPF is unknown.

There are two medicines available to treat people with IPF – pirfenidone and nintedanib. These medicines do not cure IPF, but they can help slow down fibrosis of the lungs.

Many people with IPF will get other health problems over time. High blood pressure in the blood vessels supplying the lungs – known as pulmonary hypertension – is an example of a health problem that can develop in people with IPF. Pulmonary hypertension is a serious condition that can cause damage to the heart.

There are no medicines to prevent or treat pulmonary hypertension in people with IPF.

This study was done because sildenafil helps people with another type of high blood pressure called pulmonary arterial hypertension.

This study also gave information about pirfenidone in people with advanced IPF, because previous studies of pirfenidone in IPF generally included people with less advanced IPF.

What were the study medicines?

This study focused on a medicine called ‘sildenafil’ added to ‘pirfenidone’.

Sildenafil added to pirfenidone was compared with a ‘placebo’ added to pirfenidone.

- You say sildenafil as ‘sil – de – na – fil’.
- You say placebo as ‘plah – see – bo’.
- You say pirfenidone as ‘pir – fe – nih – doen’.
- The placebo looked the same as sildenafil but did not contain any real medicine. This means it had no medicine-related effect on the body.
- Researchers compared sildenafil + pirfenidone with placebo + pirfenidone so they could show which benefits or side effects are actually caused by sildenafil.

What did researchers want to find out?

- Researchers did this study to compare sildenafil + pirfenidone with placebo + pirfenidone – to see how well sildenafil worked (see section 4 “What were the results of the study?”).
- They also wanted to find out how safe sildenafil + pirfenidone was – by checking how many people had side effects during this study (see section 5 “What were the side effects?”).

The main question that researchers wanted to answer was:

1. Did the addition of sildenafil to pirfenidone reduce the number of people who got worse – known as disease progression – over 1 year?

Other questions that researchers wanted to answer included:

2. Did the addition of sildenafil to pirfenidone reduce the changes in how well people's lungs worked over 1 year?
3. Did people feel that the addition of sildenafil to pirfenidone reduced their symptoms or improved their quality of life over 1 year?

What kind of study was this?

This study was a 'Phase II' study. This means that pirfenidone had been tested in a number of people before this study – but this was the first study in people with advanced IPF at risk of pulmonary hypertension.

Pirfenidone is approved for the treatment of adults with IPF. Sildenafil is approved for the treatment of adults with a condition called pulmonary arterial hypertension. However, the combination of pirfenidone and sildenafil has not been tested before in people with advanced IPF at risk of pulmonary hypertension.

Everyone in this study took pirfenidone – which has been shown to benefit people with IPF. People in the study were split into two groups. One group took sildenafil added to pirfenidone and the other group took a placebo added to pirfenidone. This was so researchers could see if adding sildenafil to pirfenidone gave any benefits or side effects in addition to the benefits or side effects expected from pirfenidone.

This study was 'randomised'. This means that it was decided by chance which of the two treatment groups people were assigned to – like tossing a coin.

This was a 'double-blind' study. This means that neither the people taking part in the study nor the study doctors knew which people were taking sildenafil and which people were taking placebo.

'Blinding' of a study is done so that any effect seen from the medicine is not due to something people expected to happen – if they had known which medicine they were taking.

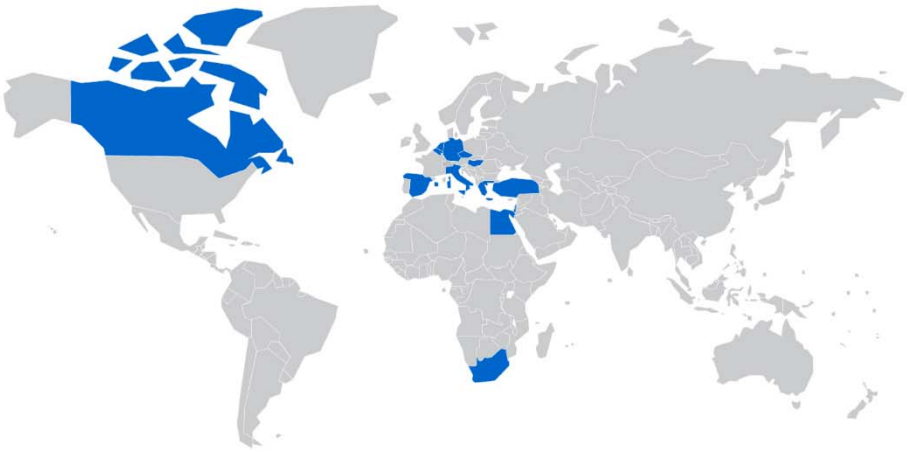
When and where did the study take place?

The study started in January 2017 and will end in August 2020. This study has two parts. The first part of the study looked at how well sildenafil added on top of pirfenidone worked over 1 year – known as efficacy – and how safe this medicine was. At the end of the first part of the study, people stopped taking sildenafil, but continued to take pirfenidone for another 11 months (second part of the study). The second part of the study is still happening, and is focusing on how safe long-term treatment with pirfenidone is.

At the time of writing this summary, the second part of the study is still taking place. However, to make the results available to the public as soon as possible, this summary presents the results from the first part of the study. The results from the second part of the study will be available at a later date.

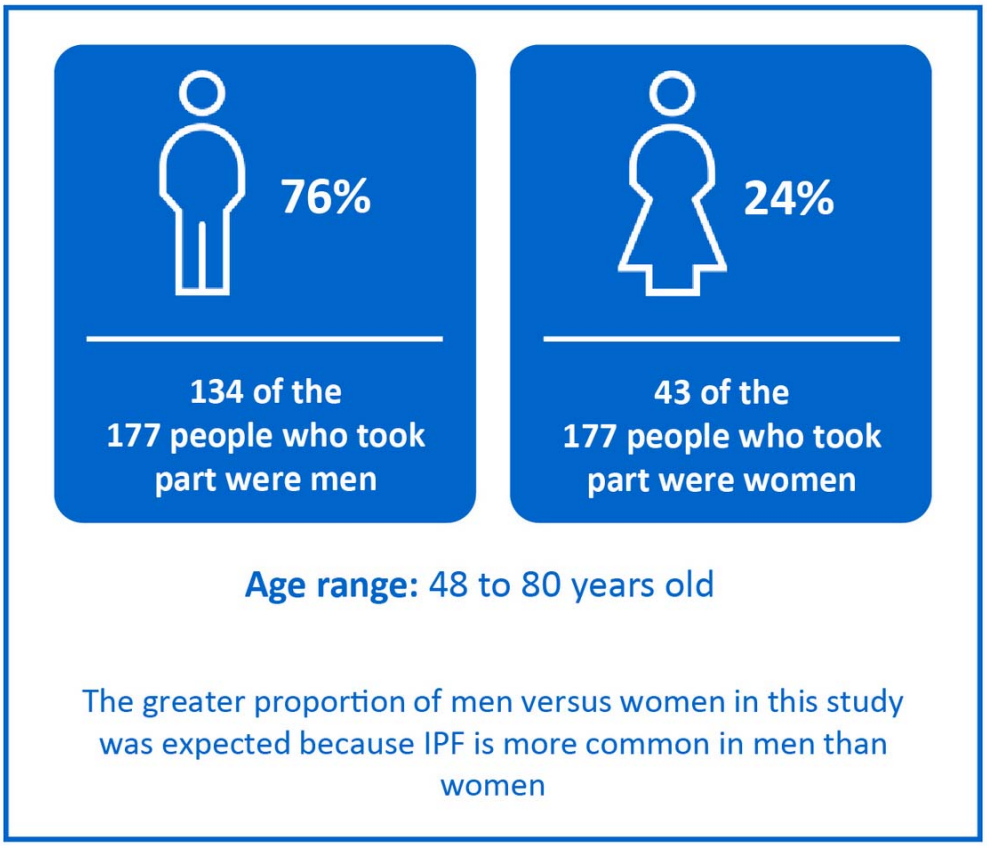
The study took place at 56 study centres – across 13 countries. The following map shows the countries where this study took place.

Belgium
Canada
Czech Republic
Egypt
Germany
Greece
Hungary
Israel
Italy
Netherlands
South Africa
Spain
Turkey



2. Who took part in this study?

In this study, 177 adults with advanced IPF took part.



People could take part in the study if:

- They had advanced IPF – measured by looking at how well their lungs could move oxygen into the blood.
- They were at risk of pulmonary hypertension – meaning they either had pulmonary hypertension or were at risk of getting pulmonary hypertension.
    - Doctors could use either one of two methods to decide if a person was at risk of pulmonary hypertension.
        - A type of ultrasound scan that lets doctors look at the heart and nearby blood vessels – known as an echocardiogram.
        - A procedure where doctors insert a catheter into the person's blood vessels – usually starting in their groin or arm – and move it to the heart – known as right heart catheterisation.
- They had been taking pirfenidone for at least 3 months before the start of the study.

People could not take part in the study if:

- They had pulmonary hypertension due to a reason other than IPF.
- They had any other serious health problems.
- They were taking certain medicines.

3. What happened during the study?

During the study, people were assigned to one of two groups – it was decided by chance which of the two groups people were assigned to. The groups were selected at random – by a computer.

The treatment groups were:

- **Sildenafil (the study medicine) + pirfenidone.**
- **Placebo + pirfenidone.**

People took their assigned treatments for 1 year.

People in the sildenafil + pirfenidone group received:

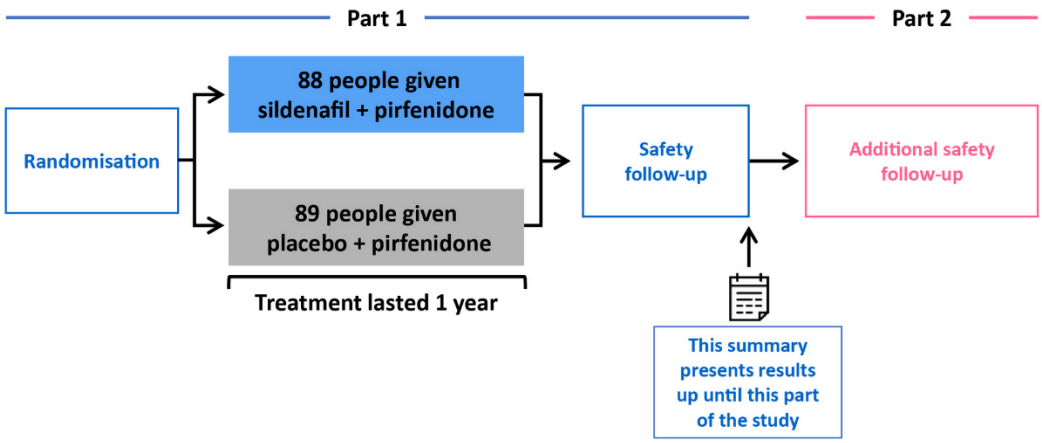
- Sildenafil – one 20 mg tablet placed inside a capsule – so the medicine looked identical to the placebo – taken by mouth, three times a day.
- Pirfenidone – two or three 267 mg capsules, taken by mouth, three times a day.

People in the placebo + pirfenidone group received:

- Placebo – one capsule, taken by mouth, three times a day.
- Pirfenidone – two or three 267 mg capsules, taken by mouth, three times a day.

Study design (with more detail underneath)

The design of this study is shown in the figure below. More information about the study design can be found underneath the figure.



Part 1 of the study included:

- **Randomisation** – selection of people to take part in the study.
- **Treatment** – people took sildenafil + pirfenidone or placebo + pirfenidone for 1 year.
- **Safety follow-up** – people stopped taking sildenafil/placebo – but kept taking pirfenidone – and were followed up for 4 weeks.

Part 2 of the study includes:

- **Additional safety follow-up** – after the first part of the study ended, people stayed in the study and kept taking pirfenidone. Doctors will continue to check the health of participants for up to 11 months.

4. What were the results of the study?

Question 1: Did the addition of sildenafil to pirfenidone reduce the number of people who got worse – known as disease progression – over 1 year?

Researchers looked at how many people in each treatment group got worse – known as disease progression – over 1 year.

A person was considered to have experienced disease progression if they had one or more of the following events during the year of treatment:

- If the number of metres they could walk in 6 minutes decreased by a set amount compared with the start of the study.
- If they had an unplanned overnight stay in a hospital for a problem related to their lungs.
- If they died.

There was only a small difference between the treatment groups in the percentage of people who experienced disease progression over 1 year.

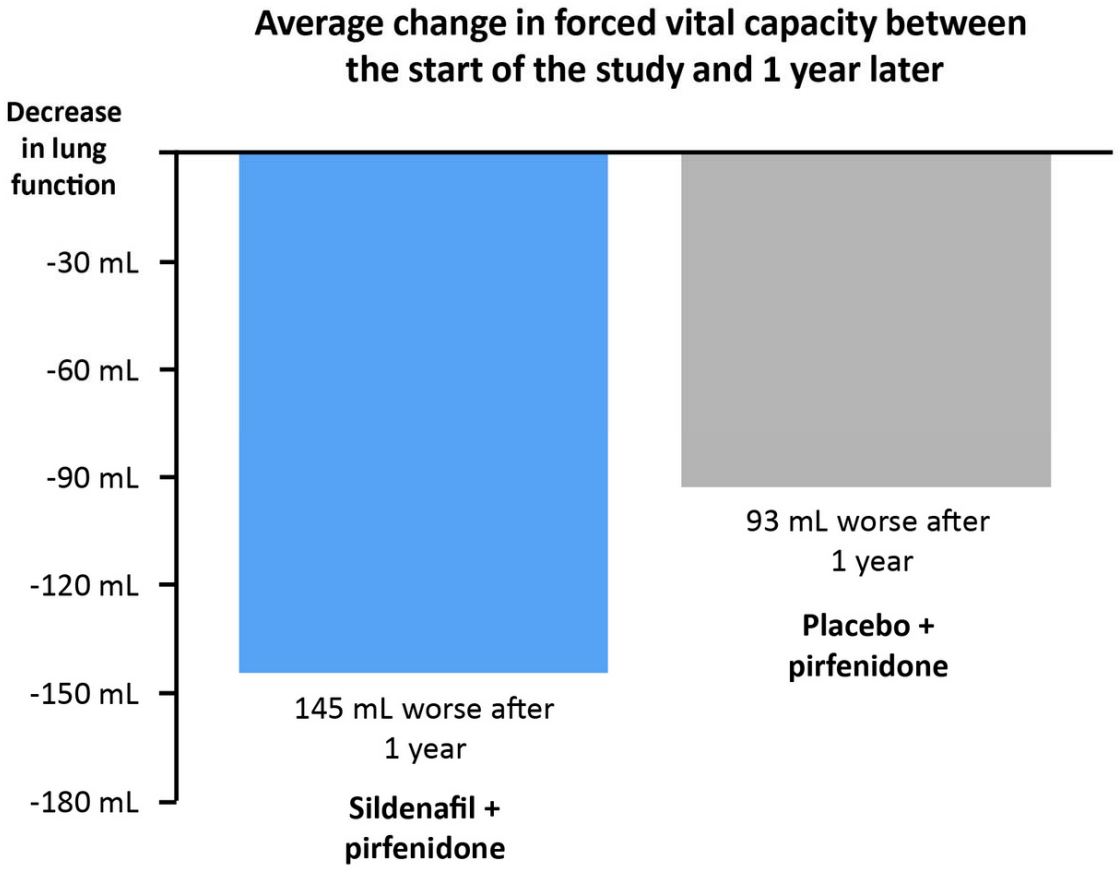
There were only small differences between the treatment groups in the percentages of people who experienced each of the individual disease progression events. These differences were too small to be meaningful.

What percentage of people experienced disease progression in each treatment group?

Question 2: Did the addition of sildenafil to pirfenidone reduce the changes in how well people's lungs worked over 1 year?

Researchers also measured how much air participants could breathe out after taking as big a breath as possible – known as forced vital capacity. Researchers wanted to know how much forced vital capacity changed between the start of the study and after 1 year. They compared the changes in the two treatment groups to see if there was a difference.

Forced vital capacity got worse in both treatment groups between the start of the study and after 1 year. It was not possible to tell if the difference between the treatment groups was due to sildenafil or if there was another reason.



Pirfenidone has previously been shown to slow down lung function decline in people with IPF. However, few people with advanced IPF were included in these studies.

The results of the study reported here suggest that pirfenidone may also benefit people with advanced IPF.

Question 3: Did people feel that the addition of sildenafil to pirfenidone reduced their symptoms or improved their quality of life over 1 year?

IPF cannot be cured, but some treatments can help reduce the impact of symptoms on everyday life. The researchers asked people in the study to complete two surveys that asked about their breathlessness and their quality of life. Someone's quality of life is the extent to which their life is comfortable or satisfying, defined in terms of health and happiness.

- Breathlessness and quality of life got worse in both treatment groups between the start of the study and after 1 year.
- The differences between the two groups were too small to tell if sildenafil had an effect on breathlessness or quality of life.

This section only shows the key results from the study at this point. You can find information about all other results on the websites at the end of this summary (see section 9 "Where can I find more information?").

5. What were the side effects?

Side effects (also known as 'adverse reactions') are unwanted medical problems (such as a headache) that happen during the study.

- They are described in this summary because the study doctor believes these side effects were related to the treatments in the study.
- Not all of the people in this study had all of the side effects.

Serious and common side effects are listed in the following sections.

Serious side effects

A side effect is considered 'serious' if it is life-threatening, needs hospital care or causes lasting problems.

During this study, less than 1 in every 10 people (3%) had at least one serious side effect that may have been related to one of the study medicines. Around 2% of people taking sildenafil + pirfenidone had a serious side effect, compared with 4% of people taking placebo + pirfenidone.

Six serious side effects that the study doctor believed were related to the treatments in the study were reported. Two happened in people taking sildenafil + pirfenidone and four happened in people taking placebo + pirfenidone. These side effects are shown in the table below.

Serious side effects reported in this study	**People taking sildenafil + pirfenidone** (88 people total)	**People taking placebo + pirfenidone** (89 people total)
Liver problems	0% (0 out of 88)	1% (1 out of 89)
Heart failure	1% (1 out of 88)	0% (0 out of 89)
Breathlessness	1% (1 out of 88)	0% (0 out of 89)
IPF getting worse	0% (0 out of 88)	1% (1 out of 89)
Weakness	0% (0 out of 88)	1% (1 out of 89)
Seizure	0% (0 out of 88)	1% (1 out of 89)

Some people taking part in the study died:

- 15 out of 88 people (17%) in the sildenafil + pirfenidone group.
- 18 out of 89 people (20%) in the placebo + pirfenidone group.

Among the people who died, some died due to side effects that may have been related to one of the study medicines:

- 1 out of 88 people (1%) in the sildenafil + pirfenidone group.
- 1 out of 89 people (1%) in the placebo + pirfenidone group.

During the study, some people decided to stop taking sildenafil or placebo because of side effects that the study doctor believed were related to the treatments in the study:

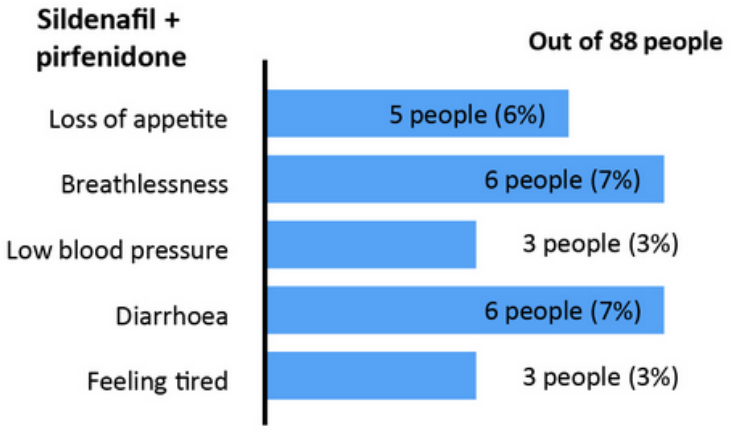
- 8 out of 88 people (9%) in the sildenafil + pirfenidone group.
- 5 out of 89 people (6%) in the placebo + pirfenidone group.

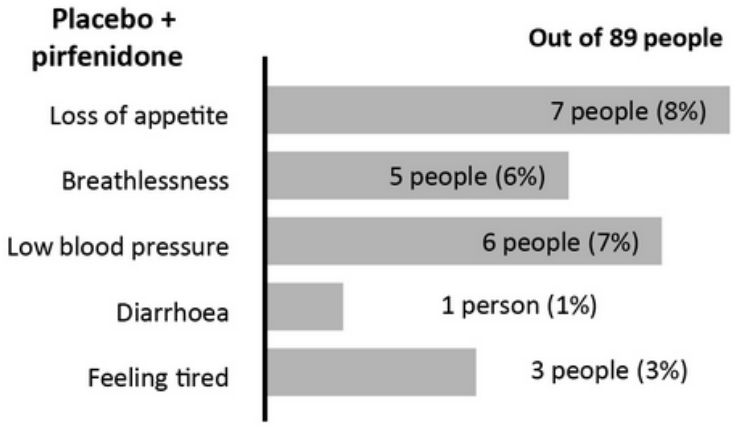
Most common side effects

During this study, 34% of people overall had a side effect that may have been related to one of the study medicines. Around 35% of people taking sildenafil + pirfenidone had a side effect, compared with around 34% of people taking placebo + pirfenidone.

There were some small differences between treatment groups in the percentages of patients with each type of side effect, but these changes were too small to tell if the difference between the treatment groups was due to sildenafil or if there was another reason.

The most common side effects are shown in the following visual – these were the five most common side effects in people who took part in the study.





Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 9 “Where can I find more information?”.

6. How has this study helped research?

These results helped researchers learn more about the effectiveness and safety of sildenafil added to pirfenidone in people with advanced IPF at risk of pulmonary hypertension – meaning they either had pulmonary hypertension or were at risk of getting pulmonary hypertension.

Key findings from this study:

- The addition of sildenafil to pirfenidone did not show any benefit compared with the addition of placebo to pirfenidone in people with advanced IPF at risk of pulmonary hypertension.
    - The percentage of people who experienced disease progression over 1 year was similar in both treatment groups.
    - Lung function – measured using forced vital capacity – got worse in both treatment arms between the start of the study and after 1 year. It was not possible to tell if the difference between the treatment groups was a true difference or if it was just due to chance.
    - Shortness of breath and quality of life got worse between the start of the study and after 1 year in both treatment groups. The differences between the two groups were too small to tell if sildenafil had an effect on shortness of breath or quality of life.
- No new safety concerns were identified in people with advanced IPF who took sildenafil + pirfenidone.
- Pirfenidone has previously been shown to help slow down lung function decline in people with IPF. However, not many studies have looked at the efficacy and safety of pirfenidone in people with advanced IPF.
    - This study suggests that pirfenidone might also slow down lung function decline in people with advanced IPF.
    - The safety of pirfenidone in people with advanced IPF in this study was similar to that seen in previous studies in people with less advanced IPF.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.

7. Glossary

Idiopathic pulmonary fibrosis (IPF)	A rare lung disease where the lungs become scarred – known as fibrosis – and breathing becomes difficult
Lung fibrosis	Scarring in the lungs
Pulmonary hypertension	High blood pressure in the vessels supplying the lungs
Sildenafil	A medicine approved for the treatment of a type of high blood pressure in the vessels supplying the lungs called pulmonary arterial hypertension
Placebo	A placebo is made to look like a real medicine, but does not contain any real medicine

Pirfenidone	A medicine approved for the treatment of idiopathic pulmonary fibrosis
Disease progression	When a disease gets worse
Lung function	How well the lungs work
Forced vital capacity	How much air a person can breathe out after taking as big a breath as possible
Advanced IPF	IPF that has gotten worse over time and has become more severe
Randomised study	When patients are randomly assigned to a treatment group
Double-blind study	When neither the study doctors nor the people taking part in the study know what treatment group patients are in
Quality of life	Someone's quality of life is the extent to which their life is comfortable or satisfying, defined in terms of health and happiness
Adverse reactions	Unwanted medical problems that happen during a study
Side effects	Unwanted medical problems that happen during a study
Serious side effect	A side effect that is life-threatening, needs hospital care, or causes lasting problems

8. Are there plans for other studies?

At the time of writing this summary, no more studies looking at sildenafil in IPF are planned.

9. Where can I find more information?

You can find more information about this study on the websites listed below:

- https://clinicaltrials.gov/ct2/show/results/NCT02951429
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-005131-40
- https://forpatients.roche.com/en/trials/respiratory-disorder/ipf/efficacy--safety--and-tolerability-study-of-pirfenidone-in-combi.html

If you would like to find out more about the results of this study, the full title of the relevant scientific paper is: "Efficacy and safety of sildenafil added to pirfenidone in patients with advanced idiopathic pulmonary fibrosis and risk of pulmonary hypertension: a double-blind, randomised, placebo-controlled, phase 2b trial". The authors of the scientific paper are: Jürgen Behr, Steven D Nathan, Wim A Wuyts, Nesrin Mogulkoc Bishop, Demosthenes E Bouros and others. The paper is published in the journal "Lancet Respiratory Medicine", DOI: https://doi.org/10.1016/S2213-2600(20)30356-8.

Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/trials/respiratory-disorder/ipf/efficacy--safety--and-tolerability-study-of-pirfenidone-in-combi.html
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

Who organised and paid for this study?

This study was organised and paid for by F. Hoffmann-La Roche, Ltd. who have their headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is: “A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Sildenafil Added to Pirfenidone in Patients with Advanced Idiopathic Pulmonary Fibrosis and Risk of Group 3 Pulmonary Hypertension”.

The study is also known as ‘SP-IPF’.

- The protocol number for this study is: MA29957.
- The ClinicalTrials.gov identifier for this study is: NCT02951429.
- The EudraCT number for this study is: 2015-005131-40.

A study of sildenafil added on top of pirfenidone in people with advanced idiopathic pulmonary fibrosis at risk of pulmonary hypertension

This is a summary of the results of a clinical study written in August 2020 for members of the public and people who took part in the study.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know.

The results from this study may be different from other studies with the same medicine. This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.

BACKGROUND

This study was done to find out whether sildenafil could help people with advanced idiopathic pulmonary fibrosis (IPF) who are at risk of pulmonary hypertension

IPF is a rare lung disease that causes the lungs to become scarred – known as fibrosis – and makes breathing difficult

There are two medicines to treat IPF – pirfenidone and nintedanib. These medicines do not cure IPF, but they can help slow down fibrosis of the lungs

Many people with IPF get other health problems over time. High blood pressure in the blood vessels supplying the lungs – known as pulmonary hypertension – is an example

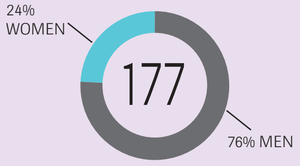
Pulmonary hypertension is a serious condition that can damage the heart. There are no medicines approved to prevent or treat pulmonary hypertension in IPF

STUDY DESCRIPTION

This study compared sildenafil + pirfenidone with placebo + pirfenidone over 1 year in people with advanced IPF who were at risk of pulmonary hypertension – meaning they either had pulmonary hypertension or were at risk of getting pulmonary hypertension – to see how well sildenafil worked and how safe it was.

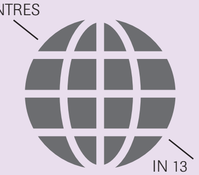
WHO TOOK PART IN THIS STUDY?

177 ADULTS WITH ADVANCED IPF AT RISK OF PULMONARY HYPERTENSION



AGE

48–80 YEARS



88 people received sildenafil + pirfenidone

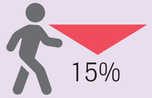
89 people received placebo + pirfenidone

FOR 1 YEAR

WHAT DID RESEARCHERS MEASURE IN THIS STUDY?

DISEASE PROGRESSION

A person was considered to have experienced disease progression if they had one or more of the following events:



If the number of metres they could walk in 6 minutes decreased by a set amount

If they had an unplanned overnight stay in a hospital because of their lungs

If they died

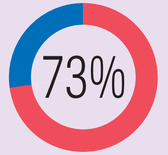
OTHER TESTS

Forced vital capacity
This is how much air they could breathe out after taking as big a breath as possible

People filled out surveys to measure how they felt about their symptoms **(shortness of breath)** and their general well-being **(quality of life)**

WHAT ARE THE MAIN RESULTS FROM THIS STUDY?

There was only a small difference between the groups in the percentage of people who had **disease progression** over 1 year. These differences were too small to be meaningful

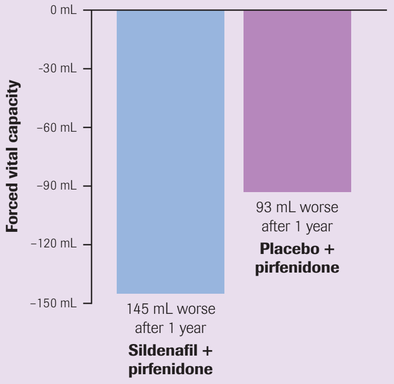


73% for sildenafil + pirfenidone

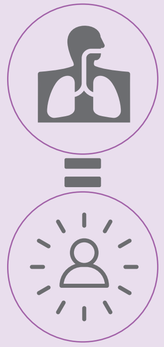
70% for placebo + pirfenidone

Forced vital capacity got worse in both groups between the beginning of the study and after 1 year

It was not possible to tell if the difference between the treatment groups was due to sildenafil or if there was another reason



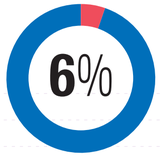
The changes between the beginning of the study and after 1 year in **shortness of breath & quality of life** were similar in both groups. The differences between the two groups were too small to tell if sildenafil had an effect on shortness of breath or quality of life



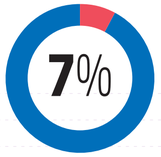
SILDENAFIL + PIRFENIDONE

35% of people had any side effect

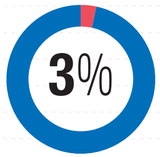
MOST COMMON SIDE EFFECTS OVERALL



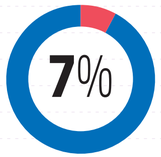
LOSS OF APPETITE



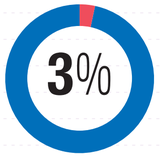
BREATHLESSNESS



LOW BLOOD PRESSURE



DIARRHOEA



FEELING TIRED

HAD A SERIOUS SIDE EFFECT

2 PEOPLE

HEART FAILURE

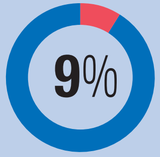
SHORTNESS OF BREATH

DIED DUE TO A SIDE EFFECT

1 PERSON

STOPPED TAKING SILDENAFIL DUE TO A SIDE EFFECT

8 PEOPLE



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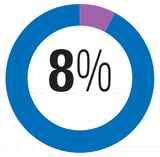
Side effects –
also known as "adverse reactions" – are unwanted medical problems (such as a headache) that happen during the study. **The side effects described in this summary are side effects the study doctor believed were related to the treatments in the study.**

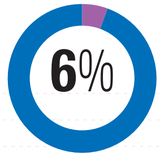
PLACEBO + PIRFENIDONE

34% of people had any side effect

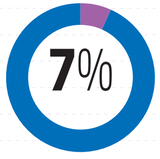
MOST COMMON SIDE EFFECTS OVERALL



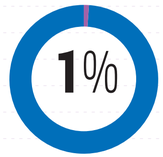
LOSS OF APPETITE



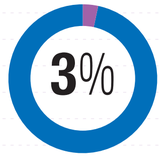
BREATHLESSNESS



LOW BLOOD PRESSURE



DIARRHOEA



FEELING TIRED

HAD A SERIOUS SIDE EFFECT

4 PEOPLE

LIVER PROBLEMS

IPF GETTING WORSE

WEAKNESS

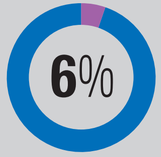
SEIZURE

DIED DUE TO A SIDE EFFECT

1 PERSON

STOPPED TAKING PLACEBO DUE TO A SIDE EFFECT

5 PEOPLE



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WHERE CAN I FIND MORE INFORMATION?

You can find more information about this study on the websites listed below:

https://clinicaltrials.gov/ct2/show/results/NCT02951429

https://www.clinicaltrialsregister.eu/ctr-search/search?query=2015-005131-40

https://forpatients.roche.com/en/trials/respiratory-disorder/ipf/efficacy--safety--and-tolerability-study-of-pirfenidone-in-combi.html

If you would like to find out more about the results of this study, the full title of the relevant scientific paper is: "Efficacy and safety of sildenafil added to pirfenidone in patients with advanced idiopathic pulmonary fibrosis and risk of pulmonary hypertension: a double-blind, randomised, placebo-controlled, phase 2b trial". The authors of the scientific paper are: Jürgen Behr, Steven D Nathan, Wim A Wuyts, Nesrin Mogulkoc Bishop, Demosthenes E Bouros and others. The paper is published in the journal "Lancet Respiratory Medicine", DOI: https://doi.org/10.1016/S2213-2600(20)30356-8.

IF YOU HAVE ANY FURTHER QUESTIONS AFTER READING THIS SUMMARY:

Visit the ForPatients platform and fill out the contact form – https://forpatients.roche.com/en/trials/respiratory-disorder/ipf/efficacy--safety--and-tolerability-study-of-pirfenidone-in-combi.html

Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results, please speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:
Speak to the doctor in charge of your treatment.

Are there plans for other studies?
At the time of writing this summary, no more studies looking at sildenafil in IPF are planned.

Who organised and paid for this study?
This study was organised and paid for by F. Hoffmann-La Roche, Ltd. who have their headquarters in Basel, Switzerland.