Clinical Trial Results – Layperson

STARLINER: A study of disease behaviour in people with suspected interstitial lung disease

Please 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 trial (called a 'study' in this document) – 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 (May 2021).

The study started in December 2017 and finished in November 2019. This summary was written after the study had ended.

No single study can tell us everything about a medical condition. 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 in a similar group of patients.

This was a study that looked at how interstitial lung diseases behaved in the time period around diagnosis. No medicines were studied by the researchers.

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Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about a group of diseases that cause scarring of the lungs – called interstitial lung diseases (ILDs) – and the behaviour of these diseases.

Key information about this study

- About interstitial lung diseases (ILDs):
  - ILDs are a group of diseases that affect the lungs.
  - There are many different types of ILD.
  - People with ILDs sometimes wait a long time for their specific type of ILD to be diagnosed.
  - This means it can take some time for people to get medicines to help treat them.
- About this study:
  - This study was done to find out more about how ILDs behaved in the time period between joining the study, through diagnosis to starting medication for ILD.
  - The idea behind this study was that finding out about how different ILDs behave could help doctors diagnose ILDs faster and start people on treatment sooner.
  - This study was performed in 6 countries and included 178 people with suspected ILD.
  - People entered the study before they had a diagnosis.
  - People were split into groups depending on the diagnosis they received during the study:
    - Idiopathic pulmonary fibrosis (IPF) – a specific type of ILD.
    - Non-IPF ILD – any type of ILD that is not IPF.
    - Non-ILD – a condition that is not an ILD.
    - No diagnosis – patients who did not receive a diagnosis while in the study.
  - People diagnosed with a non-ILD left the study on the day of diagnosis.
  - People who did not receive a diagnosis left the study after 12 months.
  - People diagnosed with IPF or a non-IPF ILD remained in the study until they started medication for their disease or for up to 6 months if no medication had been prescribed since diagnosis.
- What information was collected in this study?
  - People were given a small handheld device to take home – called a spirometer – to measure their lung function every day.
  - Researchers also measured lung function during hospital visits.
  - People were also given another small device – called an accelerometer – which counted how many steps they took each day.
  - Researchers also measured how far people could walk in 6 minutes during hospital visits – known as 6-minute walk distance.
  - People filled out questionnaires to measure their symptoms and their general well-being (quality of life).
  - Measurements taken by people at home were automatically sent to an online platform that their doctors could access. People taking part in the study could see their results on a tablet computer that was provided to them.
- Key findings from this study:
  - Differences over time in lung function were seen between people with IPF and people with a non-IPF ILD. Differences such as these might help doctors to diagnose ILDs in the future and start people on treatment sooner.
  - The difference in the change in the number of steps per day between people with IPF and people with a non-IPF ILD was too small to be meaningful.
  - The difference in the change in 6-minute walk distance between people with IPF and people with a non-IPF ILD was too small to be meaningful.

- No meaningful changes in symptoms or general well-being were seen during the study period.
- Overall – technical problems with the home measurements made it difficult for researchers to make conclusions about disease behaviour from this study.
- These results show that technical improvements are needed before home measurement technology can be an effective way of collecting information.

1. General information about this study

Why was this study done?

Interstitial lung diseases (ILDs) are a group of diseases that affect the lungs. ILDs cause scarring – known as fibrosis – inside the lungs.

There are many different types of ILD, and people with ILD sometimes wait a long time for their specific type of ILD to be diagnosed. This means it can take some time for people to get medicines to help treat them.

There are many reasons why a diagnosis can take a long time. One reason is that not a lot is known about how the different ILDs behave around the time of diagnosis.

This study was done because a better understanding of ILD disease behaviour around the time of diagnosis could help doctors to diagnose ILDs faster and start people on treatment sooner.

What was the medicine being studied?

No medicines were studied by the researchers.

What did the researchers want to find out?

Researchers did this study to find out more about how ILDs behaved in the time period between joining the study, through diagnosis to starting medication for ILD (see section 4 "What were the results of the study?").

The main question that the researchers wanted to answer was:

1. What was the change in lung function during the time period around diagnosis in people with an ILD when it was measured at home every day?

Other questions that the researchers wanted to answer included:

2. What was the change in lung function during the time period around diagnosis in people with an ILD when it was measured during hospital visits?
3. Was there a change in how active people with an ILD were during the time period around diagnosis?
4. Was there a change in symptoms or quality of life during the time period around diagnosis in people with an ILD?

What kind of study was this?

This was an international, multicentre study. This means that the study took place in different countries around the world and at multiple hospitals.

This study did not involve a medicine. This means that researchers were not using this study to find out how well a medicine worked and people were not given a specific medicine to take during the study.

When and where did the study take place?

The study started in December 2017 and ended in November 2019.

This summary was written after the study had ended.

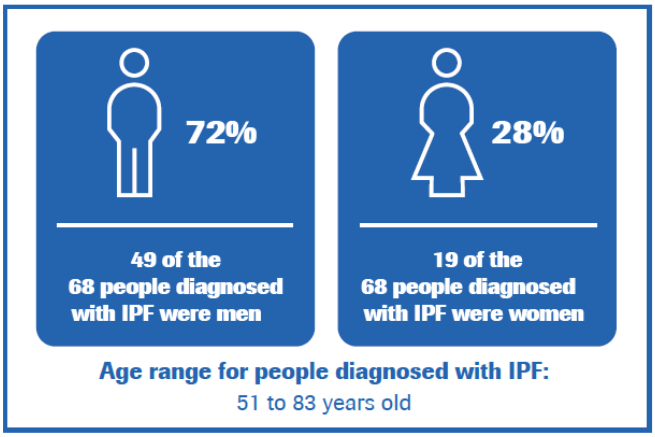
The study took place at 37 hospitals across 6 countries. The following map shows the countries where this study took place.

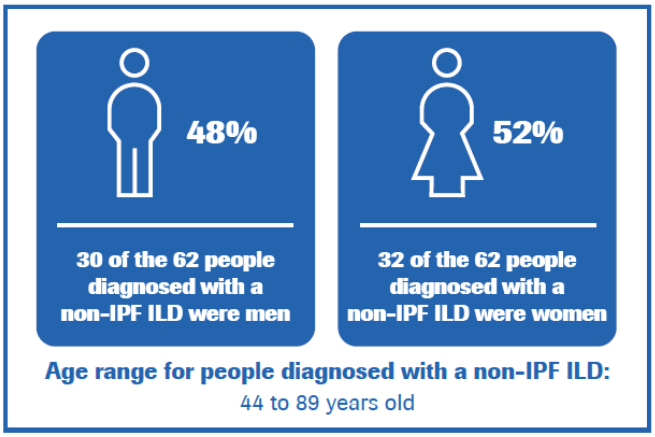
- Canada
- France
- Ireland
- Italy
- The Netherlands
- Russia

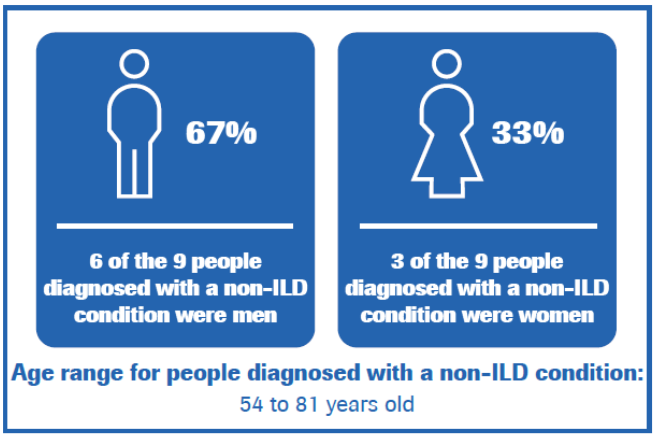
2. Who took part in this study?

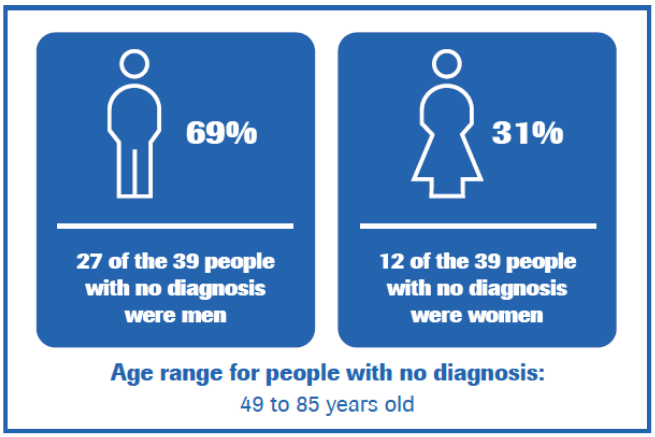
In this study, 178 people with suspected ILD took part. During the study:

- 68 people were diagnosed with IPF – a specific type of ILD.
- 62 people were diagnosed with any type of ILD that was not IPF – known as a non-IPF ILD.
- 9 people were diagnosed with a condition that was not an ILD.
- 39 people did not receive a diagnosis before they left the study.









People could take part in the study if:

- Their doctor thought they might have an ILD.

People could not take part in the study if:

- They had a history of significant heart disease.
- They had a history of connective tissue disease, for example, rheumatoid arthritis.
- They had taken part in another investigational study within 28 days of this study.

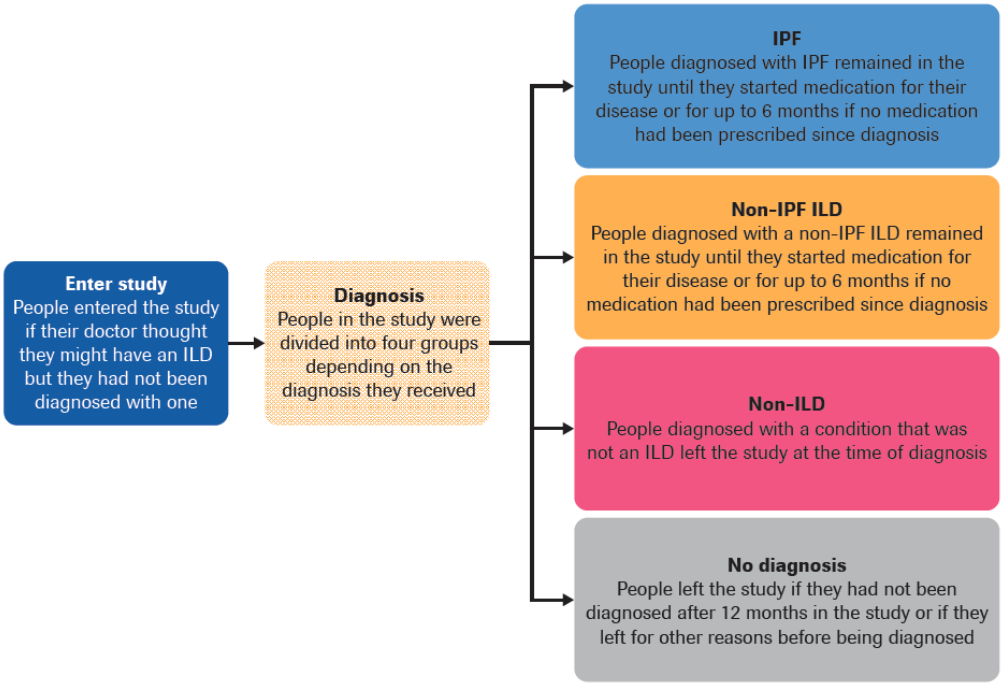
3. What happened during the study?

In this study, people were followed during the time period around diagnosis.

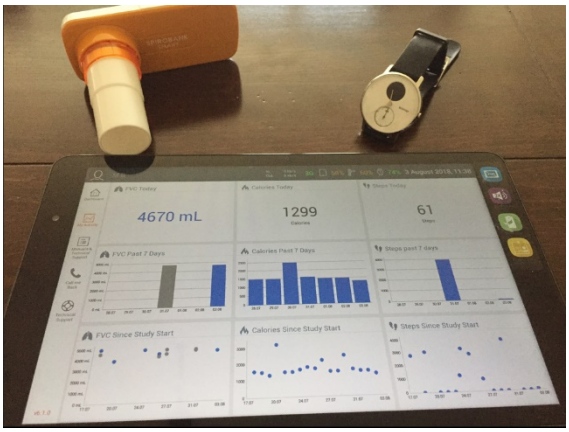
People in the study were split into groups depending on the diagnosis they were given while taking part in the study. The diagnosis groups were:

- **IPF** – people diagnosed with IPF.
- **Non-IPF ILD** – people diagnosed with any ILD that was not IPF.
- **Non-ILD** – people diagnosed with a condition that was not an ILD.
- **No diagnosis** – people who did not receive a diagnosis during the study.

The design of this study is shown in the figure below.



People in this study were followed using a combination of measurements taken at home and measurements taken at hospital.



People in this study were given a small handheld device – called a spirometer – to take home. The spirometer measured how much air they could breathe out after taking as big a breath as possible – known as forced vital capacity. Each person measured their forced vital capacity every day at home. People in the study were also given another small device – called an accelerometer. This device was worn on the wrist like a watch and it counted how many steps they took each day.

Measurements taken by people at home were automatically sent to an online platform that their doctors could access. People taking part in the study could see their results on a tablet computer that was provided to them.

4. What were the results of the study?

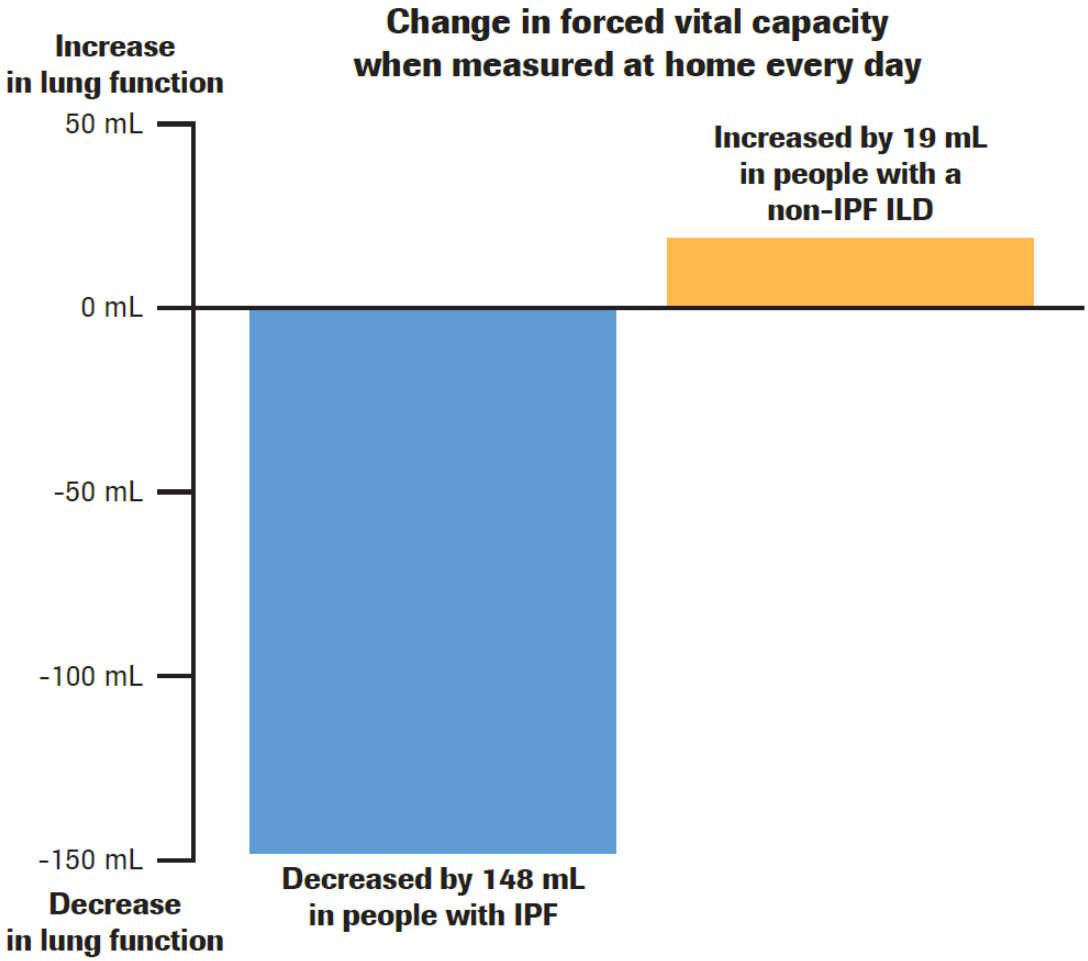
Question 1: What was the change in lung function during the time period around diagnosis in people with an ILD when it was measured at home every day?

Researchers wanted to know how much forced vital capacity changed in the time period around diagnosis in people with ILD.

However – there were some technical problems with the spirometers.

- Sometimes the spirometers did not let people take a measurement.
- Sometimes the spirometers were not able to connect to the tablet computers.
- Sometimes the spirometers did not detect when a daily blow had not been done properly and accepted the result even if it did not make sense.

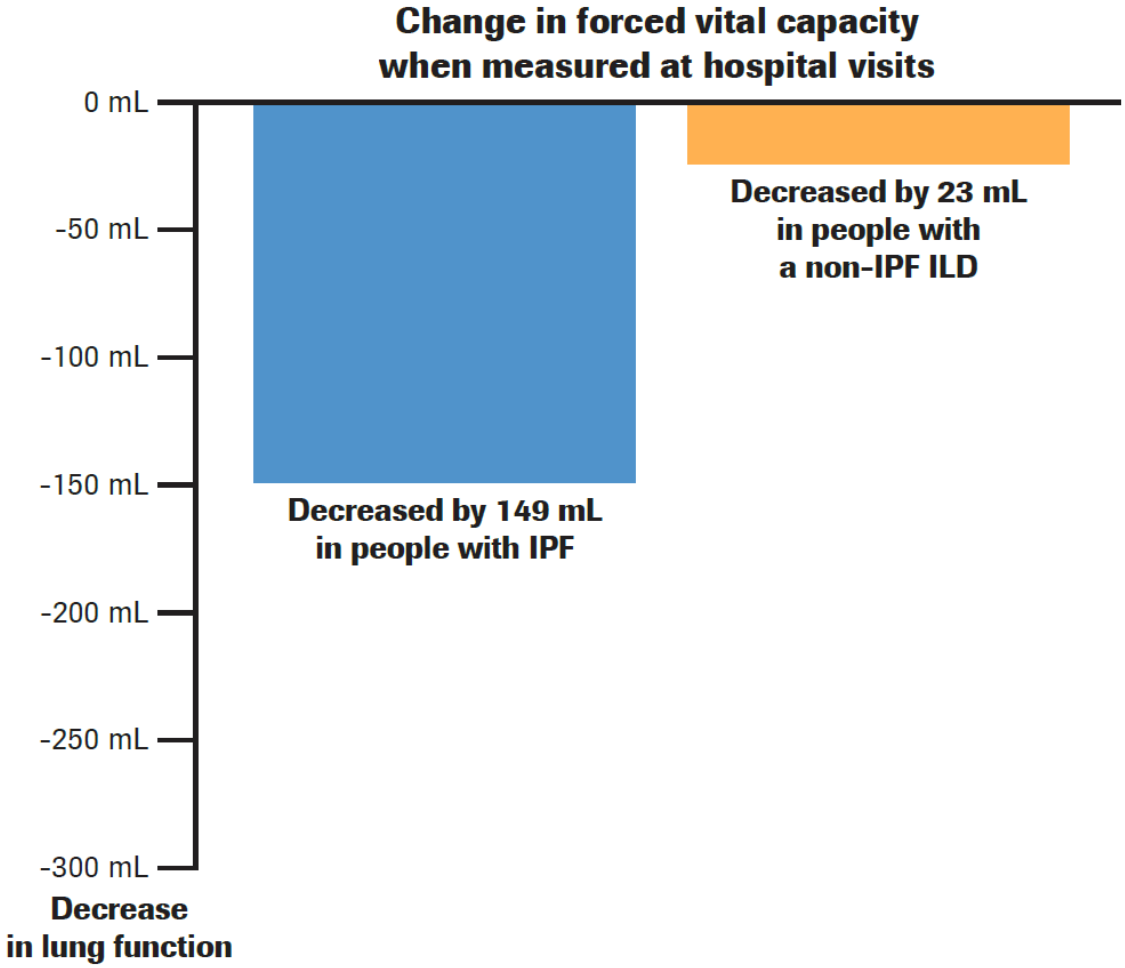
Differences in forced vital capacity were seen between people with IPF and people with a non-IPF ILD. However – technical problems with the home measurements made it difficult for researchers to make conclusions about disease behaviour from these results.



Question 2: What was the change in lung function during the time period around diagnosis in people with an ILD when it was measured during hospital visits?

Researchers also used the more common method to measure forced vital capacity in this study. People went to the hospital at least 3 times during the study and had their lung function measured while they were there.

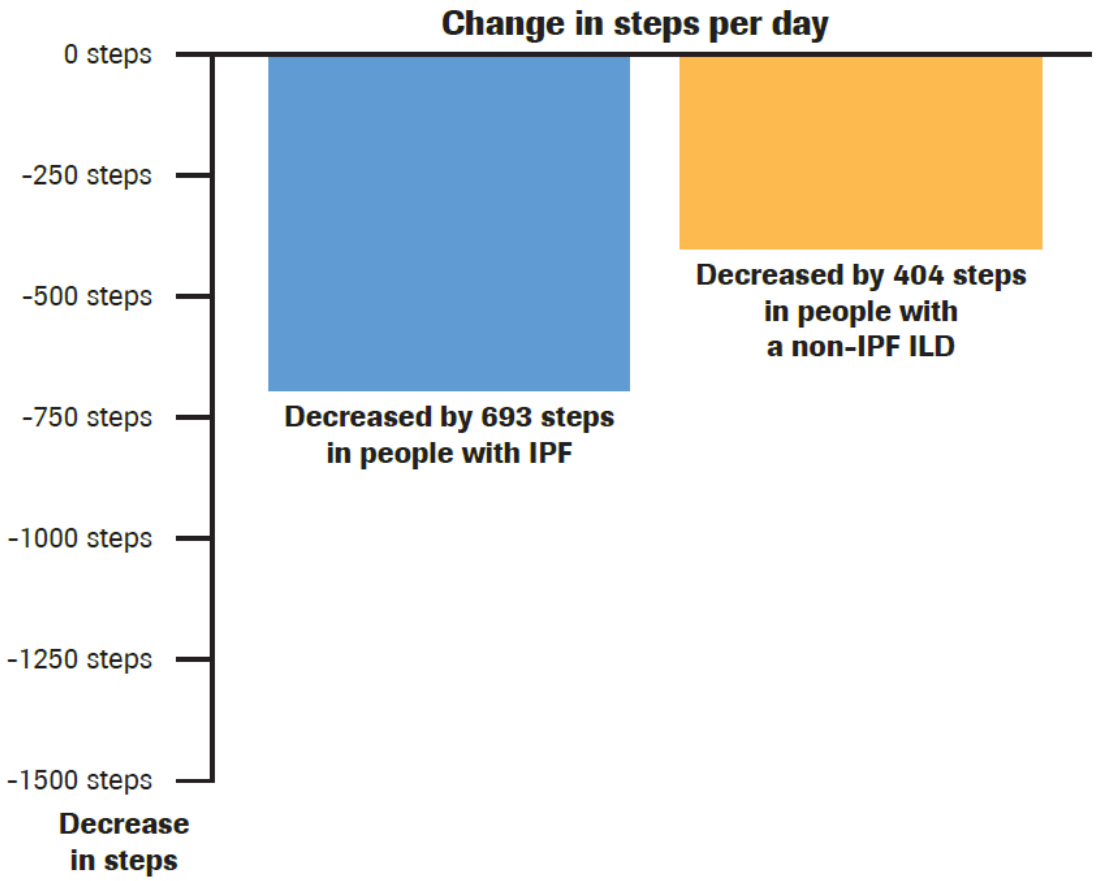
Researchers wanted to know how much forced vital capacity changed during the time period around diagnosis in people with ILD. Forced vital capacity decreased more in the group of people with IPF compared to the group of people with a non-IPF ILD.



Question 3: Was there a change in how active people with an ILD were during the time period around diagnosis?

Researchers also wanted to know how much the activity levels of people in the study changed during the time period around diagnosis.

The number of steps per day decreased more in the group of people with IPF compared to the group of people with a non-IPF ILD. The difference in the change in the number of steps per day between people with IPF and people with a non-IPF ILD was too small to be meaningful.



Researchers also looked at how far people in the study could walk in 6 minutes – known as the 6-minute walk distance.

The changes in 6-minute walk distance were small. The difference in the change in 6-minute walk distance between people with IPF and people with a non-IPF ILD was too small to be meaningful.

Question 4: Were there any changes in symptoms or quality of life during the time period around diagnosis in people with an ILD?

The researchers asked people in the study to fill out questionnaires that asked about their symptoms and their general well-being (quality of life).

There were no meaningful changes in symptoms or quality of life during the time period around diagnosis in people diagnosed with IPF, nor in people diagnosed with a non-IPF ILD.

5. What were the side effects?

People in this study were not given a specific medicine to take during the study. This means that there was no need for researchers to collect information about side effects.

6. How has this study helped research?

The information presented here is from a single study across 6 countries that included 178 people with suspected ILD.

This was the first study designed to collect information about how ILDs behave during the time period around diagnosis. The researchers hoped that finding out about disease behaviour could help doctors to diagnose ILDs faster and start people on treatment sooner.

Key findings from this study:

- In general, people were able to measure their own forced vital capacity and steps per day at home, and were able to see their results in real-time on their tablet computer.
- In the time period around diagnosis:
    - Differences in lung function were observed between people with IPF and people with a non-IPF ILD when measured at home and during hospital visits.
    - The difference in the change in steps per day between people with IPF and people with a non-IPF ILD was too small to be meaningful.
    - The difference in the change in 6-minute walk distance between people with IPF and people with a non-IPF ILD was too small to be meaningful.
    - No meaningful changes in symptoms or general well-being were seen.
    - Overall – a difference in disease behaviour was seen between people with IPF and people with a non-IPF ILD.
        - Identifying differences in disease behaviour could be a way to distinguish between IPF and a non-IPF ILD, and this may help diagnosis.
        - However – there were many technical problems with the home technology that made it difficult for researchers to make conclusions about the measurements collected.

Allowing people to take measurements at home meant that information could be collected more often and people did not have to make so many visits to the hospital. However, these results show that technical improvements are needed before home measurement technology can be an effective way of collecting information.

No single study can tell us everything about a medical condition. 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 in a similar group of patients.

This was a study that looked at how ILDs behaved. No medicines were studied by the researchers.

7. Are there plans for other studies?

At the time of writing this summary, no more studies looking at disease behaviour in people with ILD are planned.

8. 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/NCT03261037.
- https://forpatients.roche.com/en/trials/respiratory-disorder/ipf/a-study-to-characterize-the-disease-behavior-of-idiopathic-pulmo.html.

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/a-study-to-characterize-the-disease-behavior-of-idiopathic-pulmo.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 study to characterise the disease behaviour of idiopathic pulmonary fibrosis and interstitial lung disease during the peri-diagnostic period”.

The study is known as ‘STARLINER’.

- The protocol number for this study is: MA39297.
- The ClinicalTrials.gov identifier for this study is: NCT03261037.

9. Glossary

6-minute walk distance	How far a person can walk in 6 minutes – measured in metres
Accelerometer	A small device that counts how many steps a person takes each day
Clinical trial	A clinical trial – or study – is when researchers study a group of people over time The researchers regularly follow-up with the people in the study and perform medical tests
Connective tissue diseases	A group of diseases that affect the immune system and cause inflammation around the body – for example in the skin or joints, or in organs such as the kidney or lungs
Disease behaviour	How a disease presents itself – and how it changes over time
Fibrosis	Scarring
Forced vital capacity	How much air a person can breathe out after taking as big a breath in as possible
Idiopathic pulmonary fibrosis (IPF)	An illness where the lungs become scarred and breathing becomes difficult Idiopathic pulmonary fibrosis is a type of interstitial lung disease
International, multicentre study	A study that takes place in different countries around the world and at multiple hospitals
Interstitial lung diseases (ILDs)	A group of illnesses where the lungs become scarred and breathing becomes difficult
Lung function	How well the lungs work
Non-ILD	A condition that is not an interstitial lung disease
Non-IPF ILD	A type of interstitial lung disease that is not idiopathic pulmonary fibrosis
Peri-diagnostic period	The time period around (before and after) diagnosis
Quality of life	General well-being
Side effects	Unwanted medical problems that happen during a clinical trial
Spirometer	A small handheld device that measures forced vital capacity – lung function
Study centre	A place – often a hospital – where a clinical trial takes place

STARLINER: A study of disease behaviour in people with suspected interstitial lung disease

This is a summary of the results of a clinical trial, written in May 2021 for members of the public and people who took part in the study.

No single study can tell us everything about a medical condition. 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 in a similar group of patients.

This was a study that looked at how interstitial lung diseases (ILDs) behaved during the time period around diagnosis. No medicines were studied by the researchers.

BACKGROUND

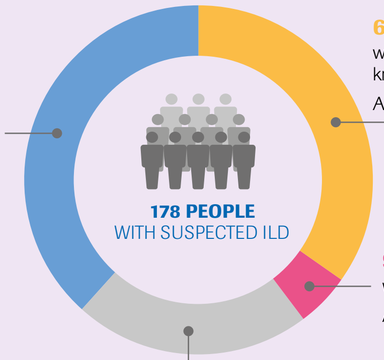
ILDs are a group of diseases where the lungs become scarred – known as fibrosis.

There are many different types of ILD and people sometimes wait a long time for their specific type of ILD to be diagnosed.

This means it can take some time for people to get medicines to help treat them.

A better understanding of ILD disease behaviour could help doctors to diagnose ILDs faster and start people on treatment sooner.

WHO TOOK PART IN THIS STUDY?



68 people
with idiopathic pulmonary fibrosis (IPF) – a specific type of ILD
Aged 51-83 years

62 people
with an ILD that was not IPF – known as a non-IPF ILD
Aged 44-89 years

9 people
with a non-ILD condition
Aged 54-81 years

39 people
who did not receive a diagnosis
Aged 49-85 years

37 STUDY CENTRES IN 6 COUNTRIES

FOLLOWED FOR UP TO 18 MONTHS

STUDY DESCRIPTION

Enter study
People entered the study if their doctor thought they might have an ILD but they had not been diagnosed with one

Diagnosis
People in the study were divided into four groups depending on the diagnosis they received

IPF
People diagnosed with IPF remained in the study until they started medication for their disease or for up to 6 months if no medication had been prescribed since diagnosis

Non-IPF ILD
People diagnosed with a non-IPF ILD remained in the study until they started medication for their disease or for up to 6 months if no medication had been prescribed since diagnosis

Non-ILD
People diagnosed with a condition that was not an ILD left the study at the time of diagnosis

No diagnosis
People left the study if they had not been diagnosed after 12 months in the study or if they left for other reasons before being diagnosed

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/NCT03261037.
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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.

ARE THERE PLANS FOR OTHER STUDIES?

At the time of writing this summary, no more studies looking at disease behaviour in people with ILD 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.

Layperson summary date: May 2021
Veeva number: M-XX-00004075

WHAT TESTS WERE USED IN THE STUDY?

Measured at home every day

People took home a small handheld device called a **spirometer** that was used to measure **forced vital capacity** – how much air they could breathe out after taking as big a breath in as possible.

People were given a small device called an **accelerometer**. This was worn on the wrist like a watch and it counted **how many steps** they took each day.

Measurements taken by people at home were automatically sent to an online platform that their doctors could access. People taking part in the study could see their results on a tablet computer that was provided to them.

Measured at hospital visits

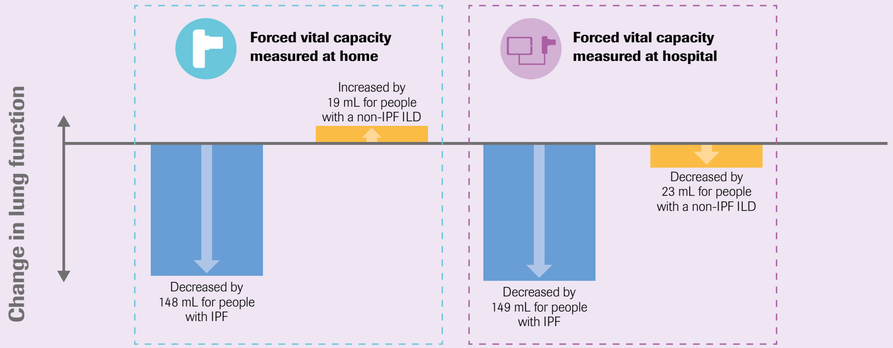
Forced vital capacity was measured by the researchers using the hospital's devices.

Researchers also looked at how far people could walk in 6 minutes – known as the **6-minute walk distance**.

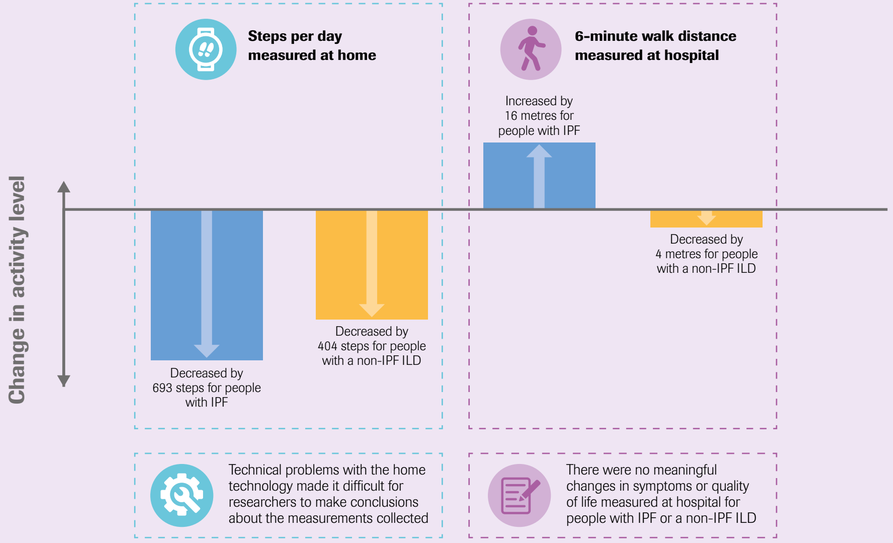
People filled out questionnaires about their **symptoms** and their general well-being (**quality of life**).

WHAT ARE THE MAIN RESULTS FROM THE STUDY?

Lung function



Activity level



Overall, a difference in disease behaviour was seen between people with IPF and people with a non-IPF ILD

These results show that technical improvements are needed before home measurement technology can be an effective way of collecting information

Layperson summary date: May 2021
Veeva number: M-XX-00004075