# Can a patient assistance program reduce the proportion of people with idiopathic pulmonary fibrosis (IPF) who stop taking pirfenidone?

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/08/2019	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
13/09/2019	Completed	Results
Last Edited	Condition category	Individual participant data
12/09/2019	Respiratory	[] Record updated in last year

#### Plain English summary of protocol

Background and study aims

Idiopathic pulmonary fibrosis (IPF) involves scarring of the lungs, causing shortness of breath and coughing. Its cause is currently unknown. Pirfenidone is a drug used to treat IPF by slowing down the scarring and reducing inflammation. This study aims to investigate whether a patient assistance program designed for people with IPF who are being prescribed pirfenidone can increase the effect of the drug on their symptoms and improve their quality of life. The patient assistance program will include information on IPF and pirfenidone, as well as information on how to recognise and prevent side effects of treatment.

#### Who can participate?

Adults with IPF who have decided with their doctor to start taking pirfenidone.

#### What does the study involve?

When a patient goes to the hospital pharmacy to collect the pirfenidone prescribed by the lung specialist, he/she will be included by the healthcare professional in the study after signing the informed consent form and confirming they are eligible. Patients eligible to enter the study will be consecutively assigned to enter the assistance program (PAP group) or continue being followed as per Standard of Care (Control group) for a minimum of 6 months. Patients in the PAP group will be periodically contacted by specialized nurses in a call center. Control group patients will continue accessing the routine standard of care from their lung specialist and other healthcare professionals involved in the management of patients with IPF.

What are the possible benefits and risks of participating?

There are no additional risks, as the participant has already decided to start taking pirfenidone and it is their decision whether to take it, whether they participate in the trial or not. The potential benefit is that those in the patient assistance program might gain a greater understanding of their condition and how to manage it.

Where is the study run from? Roche Farma (Spain)

When is the study starting and how long is it expected to run for? January 2019 to July 2022

Who is funding the study? Roche Farma (Spain)

Who is the main contact? Roche Clinical Trials Enquiries global-roche-genentech-trials@gene.com

## Contact information

## Type(s)

**Public** 

#### Contact name

Dr Clinical Trials

#### Contact details

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

ML40261

# Study information

#### Scientific Title

Impact of a patient assistance program on the persistence of treatment with pirfenidone in patients with idiopathic pulmonary fibrosis

## **Study objectives**

This non-interventional study will be conducted in Spain focusing on understanding the impact of a patient assistance program (PAP) on IPF participants.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 24/09/2018, Comité de Ética de la Investigación con medicamentos del Principado de Asturias (Hospital Universitario Central de Asturias, Avda. de Roma, s/n 33011 Oviedo, Spain; +34 9851079 27 ext. 37927/38028; ceim.asturias@asturias.org), ref: 48/18

#### Study design

Single-country prospective primary data collection non-interventional study (NIS)

### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Idiopathic pulmonary fibrosis

#### Interventions

The patients are not assigned to the treatment by the protocol but clinical practice and following the SmPC and clinical practice for dosing in both arms.

When a patient goes to the hospital pharmacy to collect the pirfenidone prescribed by the pulmonologist, he/she will be included by the healthcare professional (HP) in the study after signing the informed consent form and confirm the eligibility criteria. Patients eligible to enter the study will be consecutively assigned by a computer-generated algorithm in a 1:1 ratio to enter the assistance program (PAP group) or continue being followed as per Standard of Care (Control group) for a minimum of 6 months.

PAP group: patients in the PAP group will be periodically contacted by specialized nurses in a call center.

Control group: patients in the control group will continue accessing the routine standard of care from their pulmonologist and other HPs involved in the management of patients with IPF.

## Intervention Type

Behavioural

#### Primary outcome(s)

Time in days to permanent discontinuation of pirfenidone (i.e. time on pirfenidone) in participants allocated in PAP compared with participants who continue being followed-up as per the routine standard of care (SoC) up to 27 months

## Key secondary outcome(s))

- 1. Percentage of participants who discontinue pirfenidone within the first 6 months of treatment up to 27 months]
- 2. Reasons for discontinuing pirfenidone: type and severity of adverse events (AEs) related to IPF treatment, type and severity of AEs unrelated to IPF treatment, worsening symptoms, physician's decision, patient's decision, any other reason from baseline up to 27 months
- 3. Time and number of temporary interruptions of pirfenidone when they are communicated within the study duration from baseline up to 27 months
- 4. Time and number of dose-adjustments of pirfenidone (i.e. dose reductions) as per SmPC from baseline up to 27 months

- 5. Titrated-dose and full-dose of pirfenidone measured in mg from baseline up to 27 months 6. Adherence to pirfenidone measured by Morisky-Green (MG) questionnaire and by counting returned medication every month from baseline up to 27 months
- 7. Factors predicting adherence to and discontinuation of pirfenidone measured by patient activation measure (PAM) questionnaire at the inclusion and final visits from baseline up to 27 months
- 8. The role of psycho-morbidity (symptoms of depression and anxiety) on adherence to and discontinuation of pirfenidone measured by hospital anxiety and depression scale (HADS) score from baseline up to 27 months
- 9. Number and reasons for hospitalizations from baseline up to 27 months
- 10. Percentage of participants with adverse events (AE) from baseline up to 27 months
- 11. Functional respiratory changes of participants measured by forced vital capacity (FVC; absolute and % of predicted value), forced expiratory volume in one second (FEV1), FEV1/FVC ratio, diffusing capacity of the lungs for carbon monoxide (DLCO, percentage of predicted value), and distance on 6-min walking test (6MWT) at baseline, visits 1 and 3 and then at every 6-month visit (up to 27 months)
- 12. Degree of dyspnea and fatigue after the administration of pirfenidone measured by modified Medical Research Council (mMRC) and Fatigue Assessment Scale (FAS) score, respectively, at baseline, visits 1 and 3 and then at every 6-month visit (up to 27 months)
- 13. Severity of cough after the administration of pirfenidone measured by Visual Analog Scale (VAS) score at baseline, visits 1 and 3 and then at every 6-month visit (up to 27 months)
- 14. Quality of life of participants measured by King's Brief Interstitial Lung Disease (K-BILD) score at baseline and at last study visit
- 15. Satisfaction of participants with PAP measured by a 5-point Likert scale at the last study visit 16. Time-dependent impact of PAP on persistence rate of pirfenidone measured by the percentage of participants in the PAP group that remain on pirfenidone at different time-points

## Completion date

from baseline, up to 27 months

15/07/2022

## **Eligibility**

#### Key inclusion criteria

- 1. Participants diagnosed with idiopathic pulmonary fibrosis
- 2. Participants in whom their treating physician has decided, in partnership with them, to prescribe pirfenidone in accordance with the approved labelling
- 3. Written informed consent provided

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Concurrent participation in a clinical trial
- 2. Participants unable to give consent as per investigator criteria

#### Date of first enrolment

14/03/2019

#### Date of final enrolment

15/11/2021

## Locations

#### Countries of recruitment

Spain

#### Study participating centre

Hospital Universitari Germans Trias i Pujol; Servicio de Neumologia

Badalona

Spain

8916

#### Study participating centre

Hospital General de Albacete; Servicio de Neumologia

Albacete

Spain

2008

#### Study participating centre

Hospital del Mar; Servicio de Neumologia

Barcelona

Spain

8003

#### Study participating centre

Hospital General de Granollers; Servicio de Neumologia

Granollers

Spain

8402

#### Study participating centre

## Hospital de Cruces; Servicio de Neumologia

Barakaldo Spain 48903

## Study participating centre Hospital Lucus Augusti; Servicio de Neumologia

Lugo Spain 27003

## Study participating centre Hospital de Mataro; Servicio de Neumologia

Mataro Spain 8304

## Study participating centre

Corporacio Sanitaria Parc Tauli; Servicio de Neumologia

Sabadell Spain 8208

## Study participating centre

Hospital Arnau de Vilanova de Lleida; Servicio de Neumologia

Lleida Spain 25198

## Study participating centre

Complejo Hospitalario de Pontevedra; Servicio de Neumologia

Pontevedra Spain 36164

Study participating centre

## Hospital Universitario de Fuenlabrada; Servicio de Neumologia

Fuenlabrada Spain 28942

## Study participating centre Fundacion Hospital Alcorcon; Servicio Neumologia

Alcorcon Spain 28992

# Sponsor information

## Organisation

F. Hoffmann-La Roche AG

#### **ROR**

https://ror.org/00by1q217

# Funder(s)

## Funder type

Industry

#### Funder Name

F. Hoffmann-La Roche

## Alternative Name(s)

Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

**Switzerland** 

## **Results and Publications**

## Individual participant data (IPD) sharing plan

Participant-level data will not be available because it is confidential, proprietary information. Study data will be held at Roche Pharma S.A.

## IPD sharing plan summary

Not expected to be made available

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes