ISRCTN15587630 https://doi.org/10.1186/ISRCTN15587630

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

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
13/09/2019

Overall study status
Completed

Last Edited
12/09/2019

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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 from baseline, up to 27 months

Overall study start date

30/01/2019

Completion date

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

Age group
Adult

Sex
Both

Target number of participants
189

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
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28942

Study participating centre
Fundacion Hospital Alcorcon; Servicio Neumologia
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28992

Sponsor information

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Sponsor type
Industry

Website
https://www.roche.com/about/business/roche_worldwide.htm

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

Publication and dissemination plan
Publication is planned in a peer-reviewed journal. There is no current plan to make additional study documents available.

Intention to publish date
15/07/2023

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