

Prospective Observational Study Assessing the Impact of Elafibranor on Fatigue, Work Productivity/Activity Impairment, and Pruritus in Patients With PBC

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Study

Planned

Administrative details

EU PAS number

EUPAS1000001071

Study ID

1000001071

DARWIN EU® study

No

Study countries



United States

Study description

The purpose of this study is to understand how tiredness changes in adults with Primary Biliary Cholangitis (PBC) after starting elafibranor in routine clinical practice.

PBC is a rare liver disease that damages the small bile ducts in the liver.

Participants will complete questionnaires before starting elafibranor and at Months 3, 6 and 12. The questionnaires will ask about tiredness, itching, work and daily activities. Each participant will be followed for approximately 12 months.

Study status

Planned

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

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Institution

This study is conducted by PicnicHealth, the research vendor, on behalf of the Sponsor.

Contact details

Study institution contact

Ipsen Clinical Study Enquiries clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/12/2025

Actual: 16/12/2025

Study start date

Planned: 02/11/2026

Date of interim report, if expected

Planned: 31/08/2027

Date of final study report

Planned: 21/02/2029

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

[clin60190477 Protocol V1.0 17 July 2026_Redacted.pdf](#) (5.93 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CLIN-60190-477

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a decentralized non-interventional, descriptive, real-world study of adult participants with primary biliary cholangitis (PBC) who are newly initiating elafibranor in routine clinical practice in the US. Data will be collected through medical record retrieval and ePRO assessments.

Main study objective:

To evaluate participant-reported fatigue at baseline (pre-initiation of elafibranor) and through Month 3, Month 6, and Month 12 (M3, M6, and M12) after initiation of elafibranor for treatment of PBC (reference date).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

IQIRVO

Medicinal product name, other

ELAFIBRANOR

Study drug International non-proprietary name (INN) or common name

ELAFIBRANOR

Anatomical Therapeutic Chemical (ATC) code

(A05AX06) elafibranor

elafibranor

Medical condition to be studied

Primary biliary cholangitis

Population studied

Short description of the study population

The participants of this study will be adult participants in the United States with a documented diagnosis of PBC who are newly initiating elafibranor in routine clinical practice

Age groups

- **Adult and elderly population (≥ 18 years)**
 - Adults (18 to < 65 years)
 - Adults (18 to < 46 years)
 - Adults (46 to < 65 years)

- Elderly (≥ 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
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Special population of interest

Hepatic impaired

Estimated number of subjects

50

Study design details

Outcomes

Primary Outcome Measure:

1. Change From Baseline in PBC-40 Fatigue Domain Score
2. Change From Baseline in PROMIS Fatigue Short Form 7a Score

Secondary Outcome Measures:

Baseline Demographic and Clinical Characteristics of Participants

Change From Baseline in WPAI-SHP Absenteeism Score

Change From Baseline in WPAI-SHP Presenteeism Score

Change From Baseline in WPAI-SHP Overall Work Impairment Score

Change From Baseline in WPAI-SHP Activity Impairment Score

Change From Baseline in PBC-40 Emotional Domain Score

Change From Baseline in PBC-40 Social Domain Score

Change From Baseline in PBC-40 Cognitive Domain Score

Change From Baseline in PBC-40 General Symptoms Domain Score

Change From Baseline in PBC-40 Itch Domain Score

Data analysis plan

This study is descriptive in nature. Analyses are intended to characterize longitudinal patterns in participant-reported outcomes and clinical variables following elafibranor initiation in routine clinical practice. No formal hypothesis testing is planned unless otherwise prespecified in the SAP. Continuous variables will be summarized using descriptive statistics, including mean, standard deviation, median, minimum, maximum and 95% confidence intervals, as appropriate. Counts and percentages will be used for categorical variables. Missing data will not be routinely imputed. Exploratory analyses may include correlation analyses and regression modelling, as appropriate, to evaluate associations between liver function parameters and participant-reported outcomes. Results of exploratory analyses will be interpreted descriptively and not as confirmatory evidence.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Data sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

Patient surveys

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No