A 9-year, Multicentre, Non-interventional, Post-authorisation Safety Study for Patients Prescribed JINARC® for Autosomal Dominant Polycystic Kidney Disease (JINARC PASS)

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Last updated: 06/06/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS12842

Study ID

38891

DARWIN EU® study

No

Study countries

Austria

Belgium

- Finland
- France
- Germany
- Italy
- Luxembourg
- Netherlands
- Norway
- Spain
- Sweden
- Switzerland
- United Kingdom

Study description

This PASS is a multicentre, prospective, observational study of patients being treated with JINARC for ADPKD to better characterise specified known risks in real world treatment through evaluation of AEs and prescribing habits, and collection of data from patients with limited information from clinical trials. Study participation will be available to physicians who have completed the appropriate education in all countries in Europe where JINARC is launched and commercially available by prescription. Physicians and patients from other regions may also be included for comprehensive or separate analysis. This study does not require any additional diagnostic, therapeutic, or monitoring procedures outside of normal medical practice.

Study status

Finalised

Research institutions and networks

Institutions

Quintiles

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pierre ENGEL

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/09/2015

Study start date

Actual: 26/09/2016

Date of final study report

Planned: 31/12/2025

Actual: 20/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Otsuka Pharmaceutical Europe Ltd

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To characterise and quantify the identified risk of idiosyncratic liver injury in JINARC treated patients with ADPKD in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

JINARC

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

3.000

Study design details

Outcomes

The incidence of patients with acceptable levels of transaminases at screening who experience an elevation of transaminase (alanine aminotransferase ALT or aspartate aminotransferase AST) ≥ 3x upper limit of normal (ULN), or an AE consistent with hepatotoxicity. • The incidence of patients who meet Hy’s laboratory criteria).• The number and percentage of patients - skin neoplasms (noting in particular basal cell carcinoma)- glaucoma• The frequency of all AEs Additional exploratory endpoints will also be assessed.

Data analysis plan

Overall and stratified (eg, age, sex, race/ethnicity, country) data summaries will be presented, where possible. The main safety analyses will be evaluating the risk of serious hepatotoxicity, rare adverse outcomes (glaucoma and basal cell carcinoma), risk with long-term use, the frequency and outcome of pregnancies, the extent of off-label use, and use and risk in patients over the age of 50 years.

Documents

Study report

156-12-299-pass-final-report_Redacted.pdf (5.68 MB)

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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