Retrospective Observational non-interventional chart review study of patients with Pulmonary Arterial Hypertension (PAH) or Chronic Thromboembolic Pulmonary Hypertension (CTEPH) in Finland (FINPAH)

First published: 28/06/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS41732

Study ID

41733

DARWIN EU® study

No

Study countries

Finland

Study description

The study is an observational, retrospective, non-interventional patient chart review study, whose population is Finnish adult patients with a confirmed diagnosis of pulmonary arterial hypertension (PAH) or chronic thromboembolic pulmonary hypertension (CTEPH), or with specific therapy for PAH or CTEPH initiated at any time between years 2008-2019. The primary aim is to investigat the real-life patient characteristics, treatment patterns and clinical outcomes of PAH and CTEPH patients in Finland during years 2008-2020. Secondary aim of the study is to examine direct and indirect costs associated with PAH and CTEPH.

Study status

Ongoing

Research institutions and networks

Institutions

Helsinki University Hospital (HYKS)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Tampere University Hospital

Finland

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Institution | Educational Institution | Hospital/Clinic/Other health care facility

University of Turku

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Institution

Tampere University Hospital Tampere, Finland, Turku University Central Hospital Turku, Finland, Oulu University Hospital Oulu, Finland, Kuopio University Hospital Kuopio, Finland

Contact details

Study institution contact

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Primary lead investigator

Markku Pentikäinen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/02/2021

Study start date

Actual: 21/04/2021

Date of final study report

Planned: 30/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag Oy

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary aim is to investigate the real-life patient characteristics, treatment patterns and clinical outcomes of PAH and CTEPH patients in Finland

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, non-interventional retrospective patient chart review study

Study drug and medical condition

Medical condition to be studied

Pulmonary arterial hypertension

Pulmonary hypertension

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)

Estimated number of subjects

450

Study design details

Outcomes

1. Patient characteristics and risk groups as defined by ESC/ERS risk assessment parameters. 2. Used treatments and treatment pathways (e.g. procedures, medication, posology, treatment duration, switch patterns or discontinuation incl. possible reason). Outcomes (e.g. annualized resource use) and treatment effects defined as comparing assessments at diagnosis of PAH (baseline) and at follow-ups (potential differentiation between ERAs as derived outcomes).

Data analysis plan

Analysis will include basic statistical analysis methods aimed to describe the results. More advanced methods (e.g. multivariate modelling) may be used and subgroup analysis can be performed, if sample size and information collected is enough for such analysis. Reporting of all data is conditional of having enough observations (absolute minimum is 5 observations).

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

Routine secondary care electronic patient registry

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