Treatment patterns in patients with pulmonary arterial hypertension

First published: 20/06/2023

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS104302

Study ID

104303

DARWIN EU® study

No

Study countries

☐ Germany

☐ United Kingdom

Study description

A cohort study to investigate the actual treatment patterns for patients with Pulmonary Arterial Hypertension (PAH) in Germany and the UK, describing (1)

the first line treatment for patients diagnosed with PAH focusing on ERA and PDE5i classes (monotherapy or combined), and (2) after how long patients initiating single therapy receive a second drug (combination therapy).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

Karin Hedenmalm

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/01/2022

Actual: 31/01/2022

Study start date
Planned: 31/01/2022

Actual: 31/01/2022

Date of final study report
Planned: 15/02/2022

Actual: 08/02/2022

Sources of funding

- EMA

Study protocol

Final Analysis Plan_Treatment patterns in PAH -To be published_CLEAN.pdf
(240.65 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The main aim of the study was to describe the first line treatment for patients diagnosed with PAH focusing on ERA and PDE5i classes (monotherapy or combined), and describe after how long patients initiating single therapy receive a second drug (combination therapy).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

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

MACITENTAN

TADALAFIL

Medical condition to be studied

Pulmonary arterial hypertension

Population studied

Short description of the study population

The study included patients with a history of pulmonary arterial hypertension (both idiopathic, secondary) identified from the IMRD databases between January 2006 to June 2021.

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

Other

Special population of interest, other

Pulmonary arterial hypertension patients

Estimated number of subjects

634

Study design details

Data analysis plan

A cohort of patients with a history of PAH (both idiopathic, secondary) was created, with follow-up starting at date of diagnosis. Study period was between January 2006 and June 2021 in IQVIA™ Disease Analyser Germany and between 1998 and 2021 in IMRD. Patients with a history of PAH were followed since their first incident prescription of either ERA and PDE5i (incident use) and treatment patterns were reported. The following variables were calculated: • Number of PAH patients • Number of PAH patients that initiated incident treatment with ERA or PDE5i • Treatment initiation patterns over time in PAH patients (overall and specifically for macitentan, tadalafil) • Number of patients initially treated with monotherapy which progressed to combination therapy, (assuming that they stayed on the initial therapy), within 1 year and respectively 2 years since start of treatment.

Documents

Study results

Study Report_Treatment patterns in PAH patients -To be published_CLEAN_final.pdf(363.93 KB)

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)

IQVIA Disease Analyzer Germany

Data source(s), other

IQVIA™ Medical Research Data (IMRD) UK

Data sources (types)

Electronic healthcare records (EHR)

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