A Post-marketing, Observational Safety Study of Quinsair (Levofloxacin Hemihydrate) in Patients with Cystic Fibrosis [CLI-LEVFLAA1-01]

First published: 20/09/2017

Last updated: 15/01/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS20990

Study ID

47438

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United Kingdom

Study description

Observational comparative cohort study using secondary data collected from patients treated with Quinsair and a comparison cohort of patients treated with other inhaled approved antibiotic therapies enrolled in the UK CF Registry in the years 2017 to 2021. The observational cohort has been extended to evaluate the safety profile of Quinsair over a three-year period (2019 to 2021) compared to other inhaled approved antibiotic therapies in CF patients who are enrolled in the German CF Registry

Study status

Ongoing

Research institutions and networks

Institutions

Cystic Fibrosis Trust

United Kingdom

First published: 01/02/2024

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Institution | Not-for-profit

German Cystic Fibrosis Registry Mainz

Contact details

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Study contact

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Primary lead investigator

Nicholas Simmonds, MD

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/03/2017

Actual: 23/03/2017

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Date of interim report, if expected

Planned: 28/02/2019

Actual: 31/01/2019

Date of final study report

Planned: 20/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Chiesi Farmaceutici S.p.A.

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

Main study objective:

To evaluate the safety profile of Quinsair over a 5-year period (2017-2021) compared to other inhaled approved antibiotic therapies in CF patients who are

enrolled in the UK CF Registry. The main objective has been enlarged with a 3-year (2019-2021) period observation in CF patients who are enrolled in the German CF Registry

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

QUINSAIR

Medical condition to be studied

Cystic fibrosis lung

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

800

Study design details

Outcomes

The occurrence of each AESI: haemotysis, hepatotoxicity, tendon rupture. Discontinuation of Quinsair and other inhaled approved antibiotic therapies due to AEs Patterns of antimicrobial resistance of P. aeruginosa isolated from Quinsair-treated patients, The occurrence of musculoskeletal events (including arthritis, arthropathy, tendinitis, other tendinopathy, tendon rupture) in patients < 18 years of age who are using Quinsair off-label.

Data analysis plan

Descriptive statistics will be produced for each indicated parameter. For continuous data, the number of observations, mean, standard deviation, median, min and max will be presented. Data will be evaluated for the presence of likely effect modifiers and confounding factors in univariate analyses. Summary and descriptive statistics for demographic and baseline characteristics will be presented for each of the cohorts. Two methods for adjusting for confounders may be used depending on sample and data availability: - Matching of treatment according to propensity scores - reweighting using inverse propensity scores weighting (IPW) as part of marginal structural models. Analyses of primary & secondary endpoints: - AESIs in adult CF patient: Number and % of patients reporting each AESI will be summarized with crude RR and 95% CI, incidence rates for each event and time-to-event analyses in both cohorts. - occurrence of musculoskeletal events in patients <18 years of age

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