Survey to assess physicians' knowledge of Exjade posology and biological monitoring recommendations as described in the Educational Materials

First published: 27/10/2023

Last updated: 13/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS104950

Study ID

104951

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] France

- [ ] Germany
- [ ] Hungary
- [ ] Italy
- [ ] Poland
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The main objective of this survey is to assess whether sufficient levels of knowledge of posology and biological monitoring recommendations as described in the Exjade EU Summary of Product Characteristics (SmPC) can be attained among prescribers of Exjade/deferasirox, through the provision of Exjade EMs (which includes a Physician’s reference checklist) developed by Novartis.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/08/2022

Actual: 23/08/2022

Study start date

Planned: 31/01/2024

Actual: 12/01/2024

Data analysis start date

Planned: 15/02/2024

Actual: 15/02/2024

Date of final study report

Planned: 20/12/2024

Actual: 10/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis AG

Study protocol

CICL670A2429 protocol V01 clean_Redacted.pdf (651.25 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CICL670A2429

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

To evaluate the effectiveness of Educational Material for Exjade (deferasirox)

Study drug and medical condition

Name of medicine

EXJADE

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

DEFERASIROX

Anatomical Therapeutic Chemical (ATC) code

(V03AC03) deferasirox

deferasirox

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

400

Study design details

Outcomes

Percentage of correct response rate to the physician survey questionnaire

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Data analysis plan

Physician knowledge will be evaluated in each of the two key sections separately: posology of Exjade, and biological monitoring recommendation for Exjade.

Success criteria of the survey will be based on the observed mean correct response rate for each section.

A threshold of correct response rate of at least 70% or more will be considered as a success for each section of the survey.

The mean correct response rate (in percentage) for each survey section is calculated taking the average of the proportion of correct responses within each section (total number of correct responses X 100/total number of questions in each section) based on all physicians participating in the survey.

Documents

Study report

CICL670A2429 icl670--physician-survey-report_Redacted.pdf (5.33 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

Survey

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