Non-Interventional Post-Authorisation Safety Study (PASS) survey to evaluate the effectiveness of the Isatuximab Educational Materials, to minimise the Risk of Interference for blood typing (minor antigen) (positive indirect Coombs' test).

First published: 03/05/2022
Last updated: 23/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48387

EU PAS number
EUPAS46988

Study ID
48387

DARWIN EU® study
No

Study countries
Austria
France
Germany
Italy
Netherlands
Poland
Sweden

Switzerland
United Kingdom

Study description
The study aims to assess the effectiveness of the isatuximab Educational Materials in terms of process indicator, meaning implementation, knowledge and behaviour with respect to the safety messages conveyed in these materials.

Study status
Finalised

Research institution and networks

Institutions

Evidera
United Kingdom
First published: 20/11/2013
Last updated
07/03/2024

Institution
Non-Pharmaceutical company
Laboratory/Research/Testing facility
ENCePP partner

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Delphine Saragoussi
Primary lead investigator

Study timelines

Date when funding contract was signed

Actual:
24/09/2020

Study start date
Planned:
02/05/2022
Actual:
09/05/2022

Data analysis start date
Planned:
31/03/2023
Actual:
20/04/2023

Date of final study report
Planned:
01/02/2024
Actual:
22/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis Groupe

Study protocol

Sanofi Isatuximab PASS survey protocol_PRAC_V1.4_21Oct2021_clean_EUPAS46988 for publication.pdf(1.85 MB)

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)

Methodological aspects

Study type

Study type:
Non-interventional study

Scope of the study:
Effectiveness study (incl. comparative)

Main study objective:
The study aims to assess the effectiveness of the isatuximab Educational Materials in terms of process indicator, meaning implementation, knowledge and behaviour with respect to the safety messages conveyed in these materials.

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

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

Medical condition to be studied
Plasma cell myeloma

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
384

Study design details

Outcomes
The primary outcome will be the % of participants who correctly respond to the key knowledge question in the assessment of education materials survey. The secondary outcomes are in addition to the primary outcome, % of prescriber HCPs who also correctly respond to at least 5 of 7 behaviour questions in the assessment of education materials survey, or % of non-prescriber HCPs who also correctly respond to at least 2 of 3 behaviour questions in the assessment of education materials survey.

Data analysis plan
A description of the following outcomes of interest related to process indicators will be performed:
• Measures of the extent of implementation of the original plan, and/or variations in its delivery, at each participating country level.
• Knowledge and Behaviour.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
LiveTracker™ panel

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