Comparison of outcomes in patients undergoing major planned surgeries before vs. after the implementation of Patient Blood Management (PBM): a retrospective study in four European countries

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/46207

EU PAS number
EUPAS43542

Study ID
46207

DARWIN EU® study
No

Study countries
Germany
Italy
Spain
United Kingdom

Study description
Anaemia is a medical condition where a component of your blood called haemoglobin (Hb) drops below a threshold (<130 g/l for men and <120 g/l for women). Iron deficiency is

considered one of the most common causes of anaemia globally. Anaemia has been associated with increased morbidity and mortality in patients who have surgery. Treatment options for anaemia include red blood cell (RBC) transfusions, oral and intravenous iron transfusions as well as red blood cell boosting agents such as erythropoietin. Patient blood management (PBM) programs plan to reduce the need for blood transfusions whilst improving patient outcomes. By encompassing all aspects of patient evaluation and management relating to the transfusion process, it ensures that patients receive optimal treatment while avoiding inappropriate treatment options. There is a need to assess the impact of PBM programs on patient outcomes in routine care for patients undergoing surgery. This multi-country, multi-centre, retrospective observational study aims to compare the outcomes of adult patients who have undergone planned surgeries before a PBM program was implemented with patients who underwent planned surgeries after a PBM program was implemented. This study will be developed in four countries in Europe: Germany, Italy, Spain and United Kingdom. In each country 1 to 3 sites will be included in the study. These sites will be selected as they are known to have implemented a PBM program within the 7-year retrospective observation period (3-years prior to, 1 year during, and 3-years post PMB implementation). All eligible patients who underwent a planned major surgery during the retrospective observation period will be included from these hospitals. The study only involves the review and analysis of historical health data collected directly from hospital databases before being anonymized. Therefore, patients will not need to undergo any study specific activities.

Study status
Ongoing

Research institution and networks

Institutions

IQVIA
United Kingdom
First published: 12/11/2021
Last updated 22/04/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Bellvitge University Hospital
First published: 01/02/2024
Last updated 01/02/2024

Institution

St. Vincentius Klinike Germany, St. Marien Hospital Germany, Humanitas Research Hospital Italy, Bellvitge University Hospital Spain, Valladolid Clinic Hospital Spain, Gregorio Marañón Hospital Spain, Glasgow Royal Infirmary United Kingdom, Campus Biomedico Italy

Contact details

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Primary lead investigator
Stone Monica
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
10/12/2020

Study start date
Planned:
01/03/2021
Actual:
30/09/2021

Data analysis start date
Planned:
28/02/2022

Date of final study report
Planned:

31/07/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Vifor

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:
Effectiveness study (incl. comparative)

Main study objective:
Compare the transfusion outcomes of patients undergoing major planned surgeries before vs. after the implementation of PBM, after adjusting for potential confounders

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Multi-country, multi-site, observational retrospective study

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
61934

Study design details

Outcomes
PRIMARY - Transfusion outcomes: - Transfusion rate, defined as percentage of patients with at least one RBC unit transfused - Nº of RBC units transfused, per patient, there are 3 categories of secondary outcomes: - Other clinical outcomes - Economic outcomes - Newly diagnosed comorbidities

Data analysis plan
The statistical analysis will be conducted with SAS® statistical software or R. Sociodemographic and clinical characteristics of study patients will be compared between the two study cohorts (pre- and post-PBM) in order to apply a propensity score-based method (PSBM) (separately by type of surgery, country and site), to balance potential confounders and allow the comparison of study outcomes between cohorts. The comparative analyses will be performed at overall level (including all types of surgeries and countries) and stratifying by type of surgery, country and site. A detailed statistical analysis plan (SAP) will be prepared and approved by the Sponsor before the data analysis initiation

Data management

Data sources

Data sources (types)
Drug dispensing/prescription data
Other

Data sources (types), other
Patients data will be extracted from hospital databases and will be fully anonymised by each site (acting as a Data Controller).

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