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

First published: 19/10/2021

Last updated: 11/03/2022

Study Ongoing

Administrative details

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 institutions 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

Study institution contact

Antonio Ramirez de Arellano

Antonio.Ramirez@viforpharma.com

Study contact

Antonio.Ramirez@viforpharma.com

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

61.934

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

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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

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)

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