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





## 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

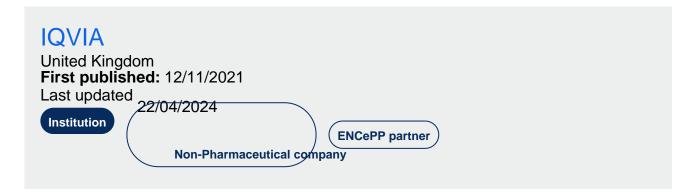
considered one of the most common causes of anaemia globally. Anaemia has been associated with increased morbidity and mortality in patients who have surgery. Treatment options for anaemia include red blood cell (RBC) transfusions, oral and intravenous iron transfusions as well as red blood cell boosting 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



**Bellvitge University Hospital** 

**First published:** 01/02/2024

Last updated

01/02/2024



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
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## 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:

# 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 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