Binocrit® in the management of preoperative anemia in patients scheduled to undergo major elective orthopedic surgery - a Prospective Observational Study (BONES)

First published: 16/03/2015

Last updated: 28/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS8398

Study ID

17958

DARWIN EU® study

No

Study countries

France

Study description

The BONES study is a National Multicenter Prospective Observational Study.Preoperative anemia in elective orthopedic surgery has been associated with increased mortality and morbidity after surgery, increased blood transfusion therapy and rates of postoperative infection leading to a longer duration of hospital stay 1. The patient hemoglobin level (Hb) before elective surgery should be within the normal range. Epoetin alfa has been shown to safely increase preoperative Hb levels in anemic patients undergoing elective noncardiac, nonvascular surgery and is more effective than preoperative autologous blood donation in reducing the need for perioperative blood transfusions in orthopedic surgery patients 2. The aim of this study is to describe Binocrit® (epoetin alfa) modalities of use and its impact on preoperative anemia evolution in patients scheduled to undergo a major elective orthopedic surgery.Pre-defined investigations or tests, which were completed as routine practice and recorded in the patient chart will be collected pertaining to: demographics and baseline patient's characteristics, medical history, clinical evaluation, Binocrit® prescription and administration, key laboratory parameters, concomitant medications, blood saving strategy, major elective orthopedic surgery features, hospitalization duration and potential complication, adverse events.All data collected will be anonymized thus protecting patient's identities.No interventional procedures or change to current medical practice are required.

Study status

Ongoing

Research institutions and networks

Institutions

Sandoz

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

RAVAKA SOUMOUDRONGA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/08/2014

Actual: 28/08/2014

Study start date

Planned: 16/03/2015

Actual: 27/03/2015

Date of final study report
Planned: 31/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANDOZ

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:

Drug utilisation

Main study objective:

Describe the evolution of hemoglobin and hematocrit (Ht) preoperative levels after Binocrit® treatment in patients scheduled to undergo a major elective orthopedic surgery.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Anaemia prophylaxis

Orthopaedic procedure

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

1000

Study design details

Outcomes

Percentage of patients achieving an Hb level > 13g/dL and/or a Ht level > 40% at the preoperative visit performed the day before or the day of the major elective orthopedic surgery. Description of patient’s characteristicsDescription of Binocrit® modalities of use and its compliance with SmPCDescription of patients requiring blood cell transfusion per and post-surgeryEvaluation of compliance with the NATA guidelines 3 and French transfusion recommendationsDescription of hospitalization duration and postoperative complicationsDescription of Binocrit® safety

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Data analysis plan

The main parameter to estimate is the percentage of patients presenting an Hb level ≥ 13g/ dL and/or an Ht rate> 40% during the preoperative period. This percentage will be evaluated with the bilateral confidence interval of 95% associated. For this parameter a multivariate logistic model will be considered with Odds ratios and associated confidence intervals of 95%. The kinetics of evolution since the anesthesia consultation (study entry, V1) to the preoperative visit (V2) will be described using a linear mixed-effects model including all data related to hemoglobin during this time range regardless of the number of entries per patient. This model considers the hemoglobin slope during this period. The same model will be used for hematocrit. A scatter plot of hemoglobin (x-axis the number of days before surgery, y-axis the value of hemoglobin) will be drawn. In these models, identified variables of the logistic model could be tested in a covariance analysis.

Documents

Study publications

Rosencher N, Poisson D, Albi A, Aperce M, Barre J, Samama CM. Two injections of…

Goodnough LT, Maniatis A, Earnshaw P, et al. Detection, evaluation, and managem…

Spahn DR. Anemia and patient blood management in knee and hip surgery: a system…

Stovall TG. Clinical experience with epoetin alfa in the management of hemoglob…

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

Prospective patient-based data collection

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