Trial Description

Title

Anaemia prevalence in surgical patients in Germany in the period 2007 - 2017 – a multicentre, retrospective study

Trial Acronym

[---]*

URL of the trial

https://www.patientbloodmanagement.de/en/pandora/

Brief Summary in Lay Language

Worldwide, approximately 30% of the total population suffer from anaemia. Those affected suffer from fatigue, paleness and limited performance, since the oxygen supply of vital organs is limited. Blood loss during surgery may aggravate anaemia and increase the risk of serious organ damage. Due to this, foreign blood transfusions are more commonly performed in anaemic patients. Nonetheless, preoperative anaemia with additional blood transfusion is associated with an increased mortality in the surgical context. Furthermore, preoperative anaemia carries a higher risk of postoperative complications and longer hospital stays.

In a global comparison, Germany is the "leader" in the use of foreign blood transfusions. The reasons for this are still unclear, but could be due to an increased prevalence of anaemia in surgical patients.

This study will cover the multi-annual course of anaemia incidence in different hospitals in Germany. In doing so, both the incidence of preoperative anaemia and hospital-acquired anaemia will be assessed taking various parameters into account.

We will investigate whether anaemia management programs could help diagnose and treat anaemia early, reduce unnecessary blood loss, and promote rational use of third-party blood products.

Brief Summary in Scientific Language

The aim of this study is the multicentre assessment of the prevalence of preoperative anaemia within the past 15 years at various German hospitals. We suspect that the prevalence of preoperative anaemia has remained stable for 15 years, or even increased. Furthermore, it is assumed that the prevalence of preoperative anaemia differs significantly between the surgical disciplines and that in the future more discipline-specific anaemia management programs should be initiated.
In the second part of the study, the prevalence of hospital-acquired anaemia will be determined taking into account the patient's age, surgical discipline, type of surgical intervention, hospital stay and time within the last 15 years.
The primary endpoint is the prevalence of preoperative anaemia (considering patient age, surgical discipline, OPS intervention, length of hospital stay, and time

within the last 10 years).
Secondary outcomes are prevalence of hospital-acquired anaemia (considering patient age, surgical discipline, OPS intervention, length of hospital stay, and time within the last 10 years), rate of deceased patients, length of hospital stay, and frequency of RBC transfusion.
Hospitals throughout Germany are contacted and motivated to participate in the study. Interested hospitals then apply for a second ethics committee vote.
Approximately 10 representative hospitals will analyse routine data of all surgical patients of March (01.03.-15.03.) in 2007, 2012 and 2017. The 2007-2017 period was selected as the RBC transfusion rate in Germany has risen rapidly in this period, but the rate of preoperative anaemia is unclear. Based on the assumption of approximately 1,000-2,000 surgical patients per month per center, there are approximately 4,000-8,000 patients per center and a total of n = 40,000-80,000 patients. Patients who undergo multiple surgeries in the selected month only enter the analysis once.
After exporting the appropriate data on age, Hb value, type of surgical intervention (OPS Code), length of hospital stay, hospital mortality rate, and RBC transfusion (yes / no) data from local hospital information systems, participating hospitals provide us with this data in an anonymised form. Subsequently, the anonymous data is evaluated and the aim is to publish the results of the study in international medical journals and in lay press.

Organizational Data

- DRKS-ID: **DRKS00016579**
- Date of Registration in DRKS: **2019/01/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **517/17 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs

Health condition or Problem studied

- ICD10: **D64.9 - Anaemia, unspecified**

Interventions/Observational Groups

- Arm 1: **The aim of this study is the multicentre assessment of the prevalence of preoperative anaemia within the past 10 years at various German hospitals. We suspect that the prevalence of preoperative anaemia has been stable for 10 years or may even have increased. Furthermore, we assume that the prevalence of preoperative anaemia differs significantly between the surgical disciplines and that in the future more discipline-specific anaemia management**

programs should be initiated.
In the second part of the study, the prevalence of hospital-acquired anaemia will be determined taking into account the patient's age, discipline, surgical intervention, hospital stay and time within the last 10 years.

- Arm 2: **No preoperative anaemia**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Historical**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Preoperative prevalence of anaemia (taking into account the age of the patient, surgical discipline, OPS intervention, hospital stay and time within the last 15 years)

Secondary Outcome

- Prevalence of hospital-acquired anaemia (taking into account the age of the patient, surgical discipline, OPS intervention, length of hospital stay and time within the last 15 years)
- Rate of deaths during hospital stay
- length hospital stay
- frequency of red cell concentrate transfusion

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Frankfurt a.M.**
- University Medical Center **Münster**

- University Medical Center **Aachen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/02/01**
- Target Sample Size: **10000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

All patients (regardless of age) undergoing surgery (OPS Code 5-01 to 5-92) in the months of March (01.03. - 15.03.) in 2007, 2012, and 2017.

Exclusion criteria

None

Addresses

- **Primary Sponsor**

  Klinik für Anästhesiologie, Intensivmedizin und SchmerztherapieUniversitätsklinikum Frankfurt
  Theodor-Stern-Kai 7
  60590 Frankfurt am Main
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Klinikum der Johann Wolfgang Goethe-Universität Frankfurt am Main
  Mr. Prof Patrick Meybohm
  Theodor-Stern-Kai 7
  60590 Frankfurt am Main

Contact for Scientific Queries

Klinikum der Johann Wolfgang Goethe-Universität Frankfurt am Main
Mr. Prof Patrick Meybohm
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Germany

Telephone: **069 6301 5998**
Fax: **[---]***
E-mail: **pandora at kgu.de**
URL: **www.kgu.de**

- **Contact for Public Queries**

Klinik für Anästhesiologie, Intensivmedizin und SchmerztherapieUniversitätsklinik Frankfurt
Mr. Prof Patrick Meybohm
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Germany

Telephone: **069 6301 5998**
Fax: **[---]***
E-mail: **pandora at kgu.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Klinik für Anästhesiologie, Intensivmedizin und SchmerztherapieUniversitätsklinik Frankfurt
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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*