ALICE: Preoperative Anaemia Prevalence in Surgical Patients – A prospective, international, multicentre observational study

Principal Investigators: Kai Zacharowski & Patrick Meybohm

Recent work estimated a global anaemia prevalence of 32.9 % meaning that more than 2.2 billion people suffer from this condition [1]. Within the surgical setting anaemia is the most diagnosed disease and affects up to 47.9 % of the patients [2]. Analysis of over 220,000 major non-cardiac surgical patients revealed that anaemia, even in mild form, is independently associated with an increased risk of morbidity and mortality [3]. Anaemia is mostly the result of an inadequate erythropoiesis due to iron deficiency (ID), lack of vitamin B12 or folate, and bone marrow diseases [4]. Among the elderly, renal or chronic disease and chronic inflammation account for approximately one-third of all anaemia incidences [5, 6]. Deficiencies in iron, folate and vitamin B12 are primarily caused by malnutrition or malabsorption. Both oral and intravenous administration of iron, vitamin B12 and folate are effective and low-cost measures to treat anaemia [7]. For example, a meta-analysis including 59 studies comprising more than 7,000 patients showed that intravenous iron was associated with a significant haemoglobin increment of 0.7 g/dL and a decreased RBC transfusion rate by 26 % [8].

At present, there is insufficient data on the proportion of surgical patients who either are deficient in iron, vitamin B12 and/or folate and/or suffer from renal anaemia or chronic disease and who might benefit from oral or intravenous administration of supplements before surgery.

The aim of the ALICE-trial is to provide detailed data about the prevalence of preoperative deficiencies in iron, vitamin B12 and/or folate and the presence of underlying renal or chronic diseases in patients undergoing major surgery. For that, patients will be screened for the presence and cause of anaemia within a self-selected week. Results will facilitate design of supplementation strategies for iron, vitamin B12 and/or folate deficiency prior to surgery, and can lay the basis for future prospective clinical trials.

Summary

Aim of the ALICE-trial: Evaluation of the prevalence and cause of preoperative anaemia in major surgical patients

Study design: prospective, international, multicentre, observational

Study period: self-selected 5-7 days

Inclusion criteria: major surgery, postoperative hospital stay ≥24h/overnight, ≥18 years

Intervention: none

Endpoints: routine data

Registration number: NCT03978260

You can fine more information in our website: www.alice-trial.com

Steering committee & national coordinators (alphabetic order):

David Baron, Vienna, Austria (national coordinator)
Elvira Bisbe, Barcelona, Spain (national coordinator)
Suma Choorapoikayil, Frankfurt, Germany
Leonie Judd, Frankfurt, Germany
Sigismond Lasocki, Angers, France (national coordinator)
Philipp Metnitz, Graz, Austria
Patrick Meybohm, Frankfurt, Germany (national coordinator)
Martin Posch, Vienna, Austria
Ravishankar Raobaikady, London, UK (national coordinator)
Martin Reichmayr, Vienna, Austria
Andrew Rhodes, London, UK
Michael Sander, Gießen, Germany
Donat Spahn, Zurich, Switzerland (national coordinator)
Kai Zacharowski, Frankfurt, Germany (national coordinator)

References

1. Lopez, A., et al., *Iron deficiency anaemia.* Lancet, 2016. **387**(10021): p. 907-16.
2. Munoz, M., et al., *Pre-operative anaemia: prevalence, consequences and approaches to management.* Blood Transfus, 2015. **13**(3): p. 370-9.
3. Musallam, K.M., et al., *Preoperative anaemia and postoperative outcomes in non-cardiac surgery: a retrospective cohort study.* Lancet, 2011. **378**(9800): p. 1396-407.
4. Shander, A., et al., *Iron deficiency anemia--bridging the knowledge and practice gap.* Transfus Med Rev, 2014. **28**(3): p. 156-66.
5. Smith, D.L., *Anemia in the elderly.* Am Fam Physician, 2000. **62**(7): p. 1565-72.
6. Weiss, G. and L.T. Goodnough, *Anemia of chronic disease.* N Engl J Med, 2005. **352**(10): p. 1011-23.
7. Butcher, A. and T. Richards, *Cornerstones of patient blood management in surgery.* Transfus Med, 2018. **28**(2): p. 150-157.
8. Litton, E., J. Xiao, and K.M. Ho, *Safety and efficacy of intravenous iron therapy in reducing requirement for allogeneic blood transfusion: systematic review and meta-analysis of randomised clinical trials.* BMJ, 2013. **347**: p. f4822.