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INNOVATIVE METHOD FOR INFECTIOUS COMPLICATIONS REDUCING AFTER ORTHOPEDIC INTERVENTIONS VIA PREVENTIVE HEMOCORRECTION. PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

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Introduction. Septic complications following orthopedic procedures remain a pressing challenge in modern surgical practice, contributing significantly to patient morbidity, prolonged hospital stays, increased healthcare costs, and, in severe cases, long-term disability. One of the modifiable but often overlooked risk factors is preoperative anemia, which is frequently underdiagnosed and undertreated. Existing evidence indicates that allogeneic blood transfusions, commonly used to correct anemia, are independently associated with a higher risk of postoperative infections. This underscores the urgent need to explore alternative, safer strategies for perioperative management, particularly those targeting the correction of anemia prior to surgery.

Aim. To evaluate the effectiveness of perioperative intravenous iron supplementation with ferric carboxymaltose in reducing the incidence of periprosthetic joint infections and improving clinical outcomes in patients undergoing elective orthopedic surgery.

Methods. The IRON study is a prospective, single-center, randomized, open-label, controlled clinical trial. A total of 170 adult patients scheduled for elective orthopedic interventions will be enrolled and randomized to receive perioperative intravenous ferric carboxymaltose at a dose of 15 mg/kg (up to a maximum of 1000 mg).

Primary endpoint. The incidence of periprosthetic joint infections within the postoperative follow-up period.

Secondary endpoints. 28-day all-cause survival, duration of stay in the intensive care unit and in the hospital, achievement of target hemoglobin levels (≥120 g/L in women, ≥130 g/L in men), number of vasopressor-free days, reduction in the frequency and volume of intraoperative and postoperative blood transfusions, and decreased utilization of the Cell Salvage System.

Expected Results: Although patient enrollment is ongoing, it is hypothesized that intravenous iron therapy will reduce the rate of infectious complications and the need for allogeneic transfusions, while improving postoperative recovery and hematologic parameters.

Key words: arthroplasty; orthopedics; periprosthetic joint infection; risk factors; preoperative care; anemia; a study protocol

INTRODUCTION

Periprosthetic joint infection (PJI) is the most serious complication after large joint re-placement surgery. Preoperative anaemia has a significant impact by inhibiting immune function and cellular processes, and believed to be a separate risk factor for periprosthetic joint infection. The connection between postoperative anaemia and PJI has been extensively researched, but the relationship between preoperative anaemia and PJI has received less attention.

Preoperative anaemia can reduce the level of C3b receptor on the erythrocyte surface, which possibly impairs immune function and increase the recovery period following surgery. This could lead to the development of periprosthetic infection. In order to prevent infectious complications after surgery, prophylactic antibiotic therapy can be used, anaemia can be corrected with haemopoietin, and chronic diseases that affect haemoglobin production can be treated. Preventing PJI following total joint replacement and lowering the risk of secondary or multiple reconstructions are preferable outcomes. Therefore, patients who meet the criteria for blood transfusion are treated with blood transfusions, prescribed iron, and erythropoietin supplements.

Early identification, evaluation and treatment of preoperative anaemia (haemoglobin < 12 g/dL for women and < 13 g/L for men) has been identified as an unmet medical need, and it has even been urged to correct preoperative anaemia by optimization of haemoglobin before planned surgery. Allogeneic blood transfusions have been shown to be an independent risk factor for increased adverse outcomes such as prolonged hospital stay and postoper-

Table 1 – Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Age ≥ 18 years 2. Informed signed consent of the patient and/or relatives (guardians) of the patient; 3. Patients scheduled for orthopedic intervention (Total knee and hip arthroplasty, revision prosthetics of large joints). 4. Laboratory and clinically confirmed diagnosis of anaemia.	1. Refusal of the patient and/or (guardians) to participate in the study, or failure to sign the informed consent; 2. Known intolerance or allergy to components of iron preparations, anticoagulants (heparin) or other components; 3. Platelet level below 50*109/l, laboratory or clinical signs of hypocoagulation, tendency to develop bleeding; 4. Acute Cerebrovascular Event 5. Acute coronary syndrome. 6. Malignant hypertension. 7. History of pulmonary embolism. 8. The presence of floating, unstable blood clots in the heart or venous system, hidden bleeding; 9. Haemolysis of any origin. 10.Blood diseases.

ative infections. Although a number of preoperative blood management techniques have been put out, few studies have assessed the relative efficacy of various approaches; hence there are no firm recommendations.

The aim of this study was to minimize the occurrence of purulent-septic complications after orthopedic interventions by applying a comprehensive therapeutic approach, including perioperative haemocorrection during the entire period of observation and hospital stay.

By potentially reducing the reliance on transfusions and decreasing the incidence of septic complications, the intervention may contribute to improved surgical outcomes and support the development of cost-effective, evidence-based perioperative care protocols in orthopedic surgery.

METHODS

Study design. This is a single-center, randomized, open-label controlled trial investigating the effect of preventive perioperative haemocorrection in order to reduce the rate of purulent-septic complications after orthopedic interventions.

Study population, inclusion and exclusion criteria. The study included 170 patients scheduled for orthopedic surgery, which met the exclusion criteria, signed informed consent, and were randomized according to the randomization scheme (table 1).

An additional 10 patients were recruited into the study in case some of the study participants decide not to participate in the study.

Before starting the study, participants must complete an informed consent form and undergo the same examination as the main group of patients. Allocation of additional patients into 2 groups was performed according to the randomization scheme of the study protocol.

The study is open-label. Due to the drug's specific colour, the comparison group cannot have a placebo control.

Blinding: To maintain the integrity of the study, the statistician and the researcher collecting the data were blinded throughout the study period and were unaware of the assigned intervention in the study groups.

Justification for inclusion criteria. 1 – the pediatric population with anaemia cannot be studied in a mixed population due to excessive variation in expected outcomes, variation in vital signs, and reference value of laboratory samples. Drug dosing should also be considered more precisely; 4 – studies including measuring the levels of red blood cells, haemoglobin, transferrin, ferritin, and serum iron will be conducted to confirm anaemia.

Justification for exclusion criteria. 1, 2 – the justification is self-evident; 3 – already taking the study drug by any route of administration may interfere with subsequent analysis; 4-10 – these groups of patients are excluded due to the possible history of use of antiplatelet agents/anticoagulants, which have a high risk of bleeding.

***Recruitment and randomization*.** All patients who are clinically eligible to participate in the study are screened for inclusion and exclusion criteria. If the patient met the study criteria, signed an informed consent to participate in the study.

Randomization was done by computer assisted randomization using permutated block de sign. Patients were randomized into experimental and control groups with a 1:1 al-location. Randomization lists are generated with a block size of 20 or 40, stratified by center. Stratifying randomization at the center helps account for potential variations or confounding factors that may be specific to each participant.

Intervention. All patients admitted for elective surgery with anemia (total knee and hip joint replacement, revision major joint replacement, correction of scoliotic deformity of the spine) were invited to participate in the study. If there was a positive response, the patient was examined according to the inclusion and exclusion criteria. Patients with clinically and laboratory confirmed anemia were included in the study. Patients will be randomized into two groups.

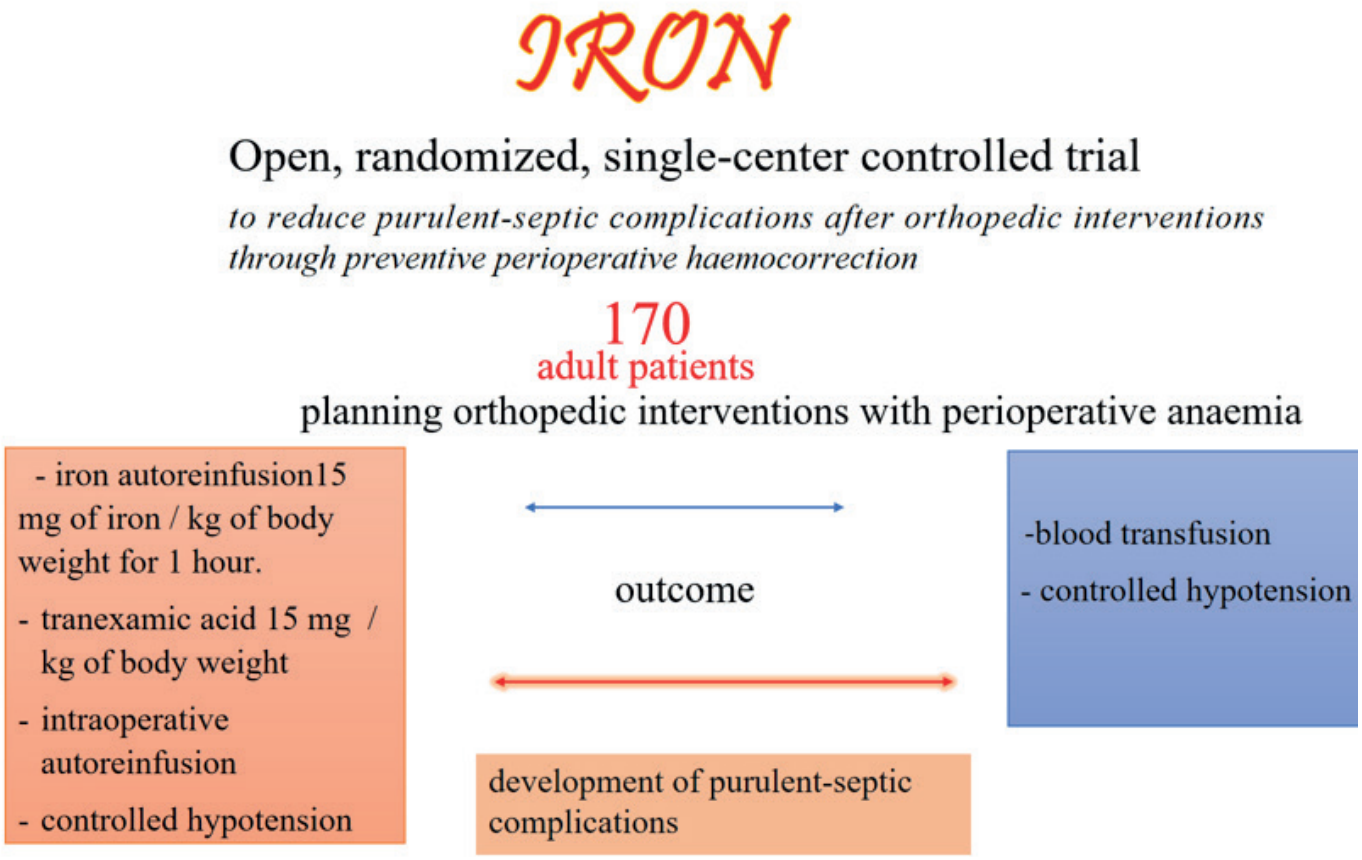

Figure 1 – The IRON study

The main group received iron carboxymaltose infusion according to body weight but not more than 1000 mg once daily preoperatively or intraoperatively and postoperatively if necessary. The dosage calculation will be carried out – 15 mg of iron/kg of body weight. The drug will be diluted only with sterile 0.9% sodium chloride solution in the volume of 200 ml. To maintain the stability of the drug, it is not recommended to dilute to a concentration of less than 2 mg iron/mL. The solution will be checked visually for the presence of particulate matter prior to use. The clinical and physical stability of the study drug has been demonstrated up to 12 hours at 30 °C, therefore the solution will be prepared accordingly (Figure 1).

The control group with anemia was prepared for surgery using standard methods of patient management without correction of iron levels (figure 2).

Regardless of the randomization group, all patients received the best available standard of care for anemia recommended by current guidelines. This includes monitoring of vital signs, optimization of hemodynamics and respiration, use of autoinfusion equipment, fibrinolysis inhibitors, fresh frozen plasma and red blood cell transfusion as needed. Surgery was performed under appropriate anesthesia, including controlled hypotension, regardless of the randomization group.

The study is an open-label study. A placebo control cannot be used in the comparison group due to the unique colour of the drug used. Blinding: The statistician and researcher collecting the data are blinded throughout the study and were unaware of the assigned intervention in the study groups to maintain the integrity of the study.

Sample size. Primary endpoints: reduction of purulent-septic complications after orthopedic interventions through preventive perioperative haemocorrection. At a confidence level of 80%, the real value is within ±5% of the measured value, meaning that 162 patients are the minimal number of samples needed to meet the desired statistical constraint. Our planned sample size is 162 patients. We will recruit an additional 5% (8 patients) to account for potential loss to follow-up and withdrawal of consent, reaching a total planned sample size of 170 patients. Secondary endpoints: 28-day survival, reduction in length of stays in the ICU and hospital, haemoglobin level for women 120 g/l, for men – 130 g/l, days without inovasopressor support, reduction in the volume and frequency of intra- and postoperative transfusion, reduction in the frequency of use of the Cell Salvage System.

Data collection and patient follow up. The following information will be collected prior to the first administration of the study drug: patient demographics, biometrics (measured or estimated), medical history, vital signs, laboratory results, ventilatory status and parameters, and vasopressor dosage. Information was also collected on the use of reinfusion devices, iron preparations, and fibrinolysis inhibitors (tranexamic acid) during the surgical procedures included in the study. Patients were followed up daily for 28 days after reinfusion (table 2).

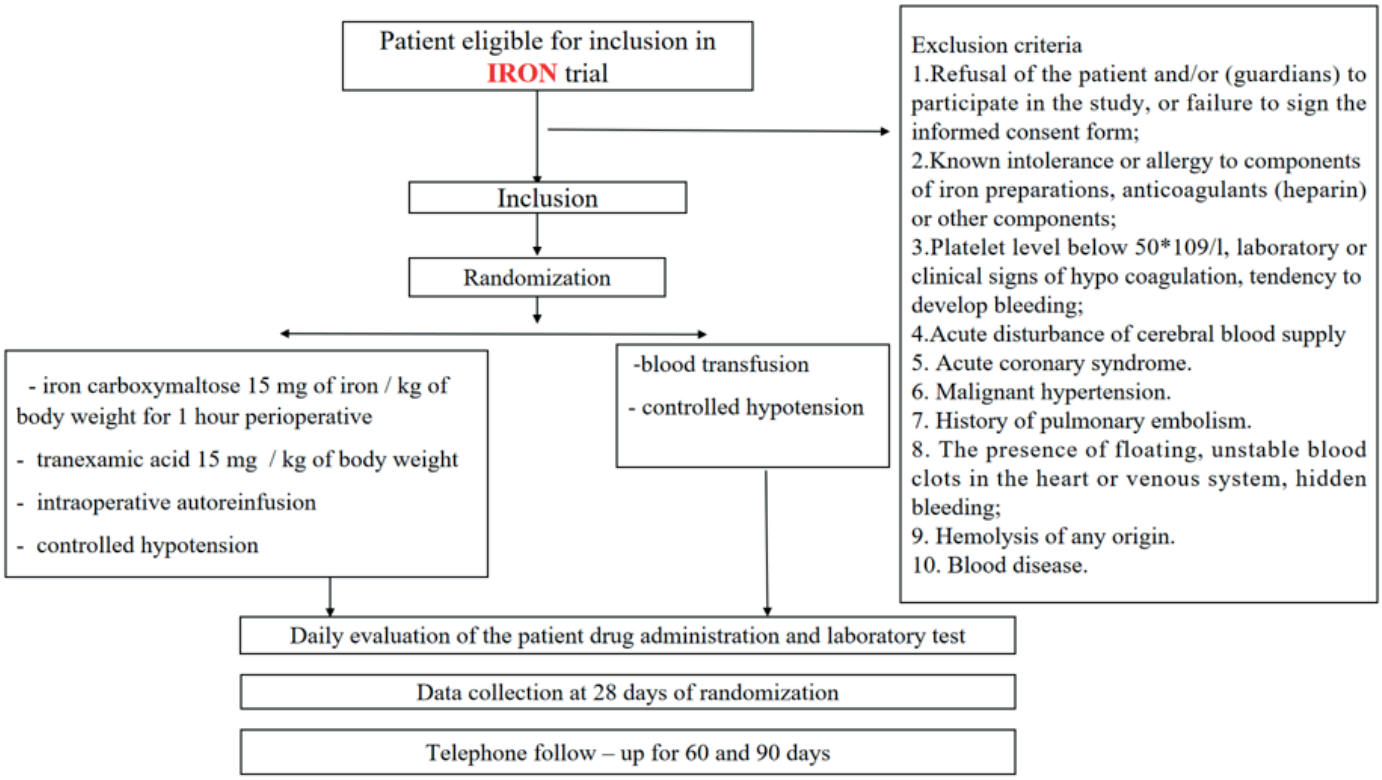

Figure 2 – The process of the study

Patients were interviewed on day 28, 60, and 90 to assess survival. Physicians visited them as scheduled if they were still in the hospital; if not, additional phone calls were made.

Statistical plan. Demographic and baseline disease characteristics are summarized using descriptive statistics. Categorical variables are presented as absolute numbers and percentages. Unadjusted univariate analyses based on Chi-square test or Fisher's exact test were used to compare the two treatment groups. Relative risks and 95% confidence intervals were calculated using the tabular two-by-two method. Continuous variables are presented as mean ± standard deviation (SD) or median and interquartile range (IQR). Intergroup differences are assessed using unpaired Student's t-test or one-sided Anova test followed by Bonferroni's post-hoc test. Baseline-corrected logistic regression models were used to estimate the treatment effect (and its 95% confidence intervals) on the primary and secondary endpoints. Statistical significance was set at a two-sided level of 0.05 for hypothesis testing. Primary data analysis is based on intention to treat analysis. Data are stored electronically in a web-based CRF form and analyzed using Stata software (Stata Statistical Software: Version 15, College Station, TX, USA).Analysis of variance is used to test hypotheses about the statistical significance of the contribution of each of these factors to the observed variability.The estimate of residual variation obtained using analysis of variance is used to calculate the 90% confidence interval for the ratio of the mean values of the corresponding parameter.

Security profile. Five-hundred and eighty four (584) iron deficiency anemia patients received either a blinded dose of IV iron carboxymaltose (15 mg/kg up to a maximum of 1000 mg in NS) or placebo over 15 minutes on Day 0. On Day 7, patients were crossed over to receive either placebo or iron carboxymaltose utilizing the same dosing as Day 0. We recorded all adverse events and classified as an adverse drug event (ADE) any that was considered by the investigator as being possibly or probably related to study drug. The mean dose of iron carboxymaltose administered was 962 (+ 88) mg. No CTC Grade 4 or 5 or serious ADE were reported and no subject discontinued from study drug due to an ADE. No clinically important differences in vital signs or physical exams were noted between subjects treated with iron carboxymaltose and placebo. During the post dose 24-h and 7-d treatment period, ADEs reported by >1% of patients in either treatment were higher in patients after receiving iron carboxymaltose than in patients after receiving placebo. The 24-h period events included nausea (2.1% iron carboxymaltose vs. 1.1% placebo), headache (2.0% vs. 1.3%), and dizziness (1.3% vs. 0.2%). The 7-d period events included nausea (2.5% iron carboxymaltose vs. 1.1% placebo), ALT increased (1.3% vs. 0.2%), AST increased (1.3% vs. 0%), headache (2.9% vs. 1.4%), dizziness (1.6% vs.0.2%) and rash (1.1% vs. 0.2%). The majority of the ADEs were classified by the investigator as mild to moderate. No ADE consistent with a hypersensitivity reaction was reported. One patient experienced a transient, asymptomatic, CTC Grade 1 decrease in BP (from 132/85 to 95/68 mmHg) which resolved spontaneously. CTC Grade 3 ADEs were reported in 4 patients after receiving iron carboxymaltose (headache and asymptomatic decrease in serum phosphate) and 5 patients (rash, creatinine increase and asymptomatic decrease in serum

Table 2 – Study monitoring

Visit number	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 28	Visit 60	Visit 90
Month of observation									
Study procedures:									
Informed consent	X								
Medical, surgical, family history	X								
Demographics	X								
Assessment based on inclusion/ exclusion criteria									
General medical examination	X								
Detailed blood test		X		X		X			
General urine analysis		X				X			
Procalcitonin		X				X			
Interleukin-6		X				X			
Serum iron		X				X			
Transferrin		X				X			
Ferritin		X				X			
Randomization		X							
Intervention				X					

phosphate) after receiving placebo. We conclude that rapid administration of high dose iron carboxymaltose (15 mg/kg for maximum of a 1,000 mg over 15 minutes) is well tolerated and associated with minimal risk of ADE in a large cohort of patients with iron deficiency anaemia [1, 2].

Ethical considerations. The study was conducted in accordance with the Declaration of Helsinki and approved by the Local Ethics Committee of the National Scientific Center of Traumatology and Orthopaedics named after Academician N.D. Batpenov (Protocol №4 from 9 November 2022).

Patients who are potential research participants will be informed about the nature of the clinical trial, the drug being studied, and the possible risks associated with taking the drug. Each patient is provided with written information about the study, contained in a patient information sheet. All patients included in the study must give written consent to participate in the study. The written consent form is filled out by the patient himself.

DISCUSSION

According to S. Yang et al. (2020), the development of purulent-septic complications following large joint endoprosthetics is particularly significant in the field of orthopedic surgery because the number of patients who can be admitted for surgical intervention with serious concomitant pathology has increased significantly due to the expansion of surgical indications, the complexity of orthopedic techniques, and the development of anesthesiology services [3].

The use of blood transfusions is associated with the risk of periprosthetic infection. For instance, a meta-analysis was carried out with a large sample of patients (n=21770), according to J.L. Kim et al. (2017). Data were obtained on patients undergoing large joint arthroplasty; for groups receiving transfusion after surgery, the risk of infection was 2.88%, and for groups not receiving blood transfusion, it was 1.74%. Surgical site infections were substantially more common in the allogeneic blood transfusion group (odds ratio (OR) = 1.71, P = 0.002) in a pooled analysis utilizing a random effects model [4].

According to J.S. Everhart et al. (2018), there is a dose-dependent correlation between the risk of surgical site infection following total hip or knee replacement and allogeneic red blood cell transfusion. Preoperative anaemia and established bleeding disorders were also risk factors for the requirement for an allogeneic red blood cell transfusion. Additionally, allogeneic red blood cell transfusion and surgical site infection were found to be dose-dependently related, with infection rates rising as transfusion doses in-creased

from one (odds ratio [OR] = 1.97; 95% confidence interval [CI] = 1. 38), 2.79; p < 0.001), up to two units (OR = 2.20; CI = 1.37, 3.44; p = 0.002), up to three units (OR = 3.66; CI = 1.72, 7.16; p = 0.001), and more than three units (OR = 7.40; CI = 4.91, 11.03; p < 0.001) after concomitant diseases, surgery, preoperative anaemia, and preoperative coagulopathies were identified. Independent risk factors for transfusion were preoperative bleeding disorder (OR = 2.09; CI = 1.57, 2.80; p < 0.001), preoperative anaemia (OR = 3.90; CI = 3.31, 4.61; p < 0.001), and a combination of haemostasis disorders (OR = 1.37; CI = 1.14, 1.64; p = 0.001) [5].

Preoperative anaemia, even moderate anaemia, is an independent risk factor for post-operative complications, according to a meta-analysis by Fowler A.J. et al. (2015), which included over 900,000 patients undergoing major surgery (including orthopedic surgery). According to the results, 30.1% (n=11,675) of 38,770 patients from 474 hospitals in 27 countries—including low-, middle-, and high-income nations had preoperative anaemia. This observational cohort study is consistent with the findings (47 3% of the studied patients had preoperative anaemia [6].

Following a post hoc examination of the pooled RECORD data (n = 12,000), it was shown that the infection rates among patients who got autologous blood and those who did not get a blood transfusion were comparable. In patients receiving allogeneic blood trans-fusion, the incidence of any infection was 9.9% (392 of 3962), but in patients not getting allogeneic blood, with or without autologous blood transfusion, it was 7.9% (646 of 8215) (p = 0.003). Patients receiving allogeneic blood transfusion had significantly higher incidence of wound inflammation or infection (2.4% [94 of 3962]) versus 1.7% [138 of 8215]; p = 0.046) and lower or upper respiratory tract and lung infections (2.1% [85 of 3962] vs. 1.3% [109 of 8215]; p = 0.002). Urinary tract infections (3.1% [123 of 3962] vs. 2.5% [209 of 8215]; p = 0.551), bone and joint infections (0.4% [14 of 3962] vs. 0.2% [18 of 8215]; p = 0.056), and other infections (3.0% [120 of 3962] vs. 2.7% [225 of 8215]; p = 0.308) does not differ significantly [7-8]. A total of 5 RCTs with 608 participants were included in the study by Peipei Guo et al. (2018). Every included study was randomized, and the majority of the included studies had a good level of quality. According to the combined data, the oral TXA group significantly exceeded the control group in terms of Hb drop (standardized mean difference [SMD], -0.936; 95% confidence intervals [CI], -1.118, -0.754), Hct drop (SMD, -0.693; 95% CI, -1.113, -0.274), and drain output (SMD, -0.793; 95% CI, -0.959, -0.628).

Between the two groups, there were no statistically significant differences in the incidence of thromboembolic consequences or transfusion rate. Due to insufficient data, the entire blood loss could not be assessed [9-11]

Diabetes mellitus is a known independent risk factor for the development of PJI. T. Jamsen et al. reported that PJI was observed in 1.59% of TGA patients and 2.19% of TKA patients with diabetes, compared with infection rates of 0.66% and 0.48%, respectively, in patients without diabetes Marchant et al compared uncontrolled diabetes with con-trolled diabetes diabetic and nondiabetic patients and found that there is a significantly increased risk of developing postoperative wound infection when diabetes is not properly controlled. A retrospective analysis showed that despite the correction of glycemic levels in patients after surgery, infections of various locations and origins were observed [12, 13].

In conclusion, in order to prevent prolonged errors in the management of patients with periprosthetic complications (long-term infusion-transfusion therapy, long-term immobilization, and polyantibacterial therapy), a protocol for preventive perioperative haemocorrection in traumatology and orthopedics should be implemented and followed after investigation.

Authors' contributions:

A. Konkayev – conceptualization, supervision.

A. Konkayev, B. Azimova – methodology.

A. Konkayev – validation, project administration, funding acquisition.

A. Konkayev, B. Azimova, N. Zhanarystan – formal analysis.

A. Konkayev – investigation.

A. Konkayev, N. Zhanarystan , B. Azimova , M. Yelgondiyeva, A. Kabibulatov, Sh. Shayakhanov – resources.

B. Azimova, N. Zhanarystan, M. Yelgondiyeva, A. Kabibulatov, Sh. Shayakhanov – data curation.

N. Zhanarystan, B. Azimova, M. Yelgondiyeva, A. Kabibulatov, Sh. Shayakhanov – writing: original draft preparation.

A. Konkayev, N. Zhanarystan – writing: review and editing.

N. Zhanarystan, B. Azimova , M. Yelgondiyeva – visualization.

Conflicts of Interest:

The authors declare no conflicts of interest.

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Institutional Review Board Statement:

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Local Ethics Committee of the National Scientific Center of Traumatology and Orthopedics named after Academician N. D. Batpenov (Protocol №4 from 09 November 2022).

Informed Consent Statement:

Written informed consent was obtained from the individual (-s) and their for the publication of any potentially identifiable images or data included in this article.

Data Availability Statement:

The data presented in this study are available on request from the corresponding author. The data are not publicly available to ensure the confidentiality of the patients' personal information.

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ИННОВАЦИОННЫЙ МЕТОД СНИЖЕНИЯ ГНОЙНО-СЕПТИЧЕСКИХ ОСЛОЖНЕНИЙ ПОСЛЕ ОРТОПЕДИЧЕСКИХ ВМЕШАТЕЛЬСТВ ПУТЕМ ПРЕВЕНТИВНОЙ ПЕРИОПЕРАЦИОННОЙ ГЕМОКОРРЕКЦИИ. ПРОТОКОЛ РАНДОМИЗИРОВАННОГО КОНТРОЛИРУЕМОГО ИССЛЕДОВАНИЯ

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Введение. Гнойно-септические осложнения после ортопедических вмешательств представляют собой актуальную проблему современной хирургии. Они связаны с увеличением продолжительности госпитализации, высоким риском инвалидизации пациентов и существенными экономическими затратами. Одним из потенциально модифицируемых факторов риска является предоперационная анемия, которая часто остаётся недооценённой и не подлежит коррекции перед операцией. Аллогенные переливания крови, традиционно применяемые для восполнения дефицита гемоглобина, продемонстрировали устойчивую связь с повышением частоты послеоперационных инфекционных осложнений. Это обосновывает необходимость поиска альтернативных и более безопасных методов коррекции анемии в периоперационном периоде.

Цель. Оценить эффективность применения карбоксимальтозы железа в периоперационном периоде для снижения частоты перипротезной инфекции и улучшения клинических исходов у пациентов, перенесших плановые ортопедические операции.

Методы. IRON — это проспективное, одноцентровое, рандомизированное, открытое, контролируемое клиническое исследование. Планируется включение 170 пациентов, подлежащих плановым ортопедическим вмешательствам. Участники будут рандомизированы на получение периоперационной инфузии карбоксимальтозы железа в дозе 15 мг/кг (максимально – 1 000 мг).

Первичная конечная точка. Частота развития перипротезной инфекции в послеоперационном периоде.

Вторичные конечные точки. 28-дневная выживаемость, длительность пребывания в отделении интенсивной терапии и стационаре, достижение целевых уровней гемоглобина (≥120 г/л у женщин, ≥130 г/л у мужчин), количество дней без вазопрессорной поддержки, объём и частота трансфузий, частота применения системы Cell Salvage.

Ожидаемые результаты. На момент подготовки аннотации набор пациентов продолжается. Предполагается, что использование карбоксимальтозы железа позволит снизить риск инфекционных осложнений, уменьшить потребность в аллогенных переливаниях и улучшить восстановление после операции.

Ключевые слова: эндопротезирование; ортопедия; перипротезная инфекция сустава; факторы риска; предоперационная терапия; анемия; протокол исследования

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ПЕРИОПЕРАЦИЯЛЫҚ АЛДЫН-АЛУ ГЕМОКОРРЕКЦИЯСЫ АРҚЫЛЫ ОРТОПЕДИЯЛЫҚ АРАЛАСУДАН КЕЙІНГІ ІРІҢДІ-СЕПТИКАЛЫҚ АСҚЫНУЛАРДЫ ТӨМЕНДЕТУДІҢ ИННОВАЦИЯЛЫҚ ӘДІСІ. РАНДОМИЗАЦИЯЛАНҒАН БАҚЫЛАНАТЫН СЫНАҚ ПРОТОКОЛЫ.

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Кіріспе. Ортопедиялық операциялардан кейінгі іріңді-септикалық асқынулар қазіргі хирургиялық тәжірибедегі өзекті мәселе болып табылады. Мұндай асқынулар пациенттің ұзақ уақыт ауруханада жатуына, мүгедектікке ұшырау қаупінің артуына және медициналық көмек шығындарының көбеюіне алып келеді. Операция алдындағы анемия – жиі кездесетін, бірақ жиі ескерілмейтін модификацияланатын қауіп факторы. Анемияны түзету үшін қолданылатын аллогендік қан құю әдістері операциядан кейінгі инфекциялық асқынулардың даму қаупін арттыратыны дәлелденген. Сондықтан операцияға дейінгі кезеңде анемияны қауіпсіз және тиімді әдістермен түзетудің баламалы жолдарын іздеу қажеттілігі туындап отыр.

Мақсаты. Периоперациялық кезеңде карбоксимальтозды темір қолданудың перипротездік инфекциялардың жиілігін төмендетудегі және клиникалық нәтижелерді жақсартудағы тиімділігін бағалау.

Әдістер. IRON – бір орталықта жүргізілетін, проспективті, рандомизацияланған, ашық, бақыланатын клиникалық зерттеу. Жоспар бойынша 170 пациентке ортопедиялық операция жасалады. Қатысушылар операцияға дейін және кейін 15 мг/кг (ең көбі – 1 000 мг) мөлшерінде карбоксимальтозды темір инфузиясын алатын топқа рандомизацияланады.

Басты нәтиже көрсеткіші: операциядан кейінгі перипротездік инфекциялардың жиілігі.

Қосымша көрсеткіштер: 28 күндік тіршілік ету, реанимация және жалпы ауруханадағы жату ұзақтығы, мақсатты гемоглобин деңгейіне (әйелдер үшін ≥120 г/л, ерлер үшін ≥130 г/л) жету, вазопрессорлық қолдаусыз өткен күндер саны, қан құю жиілігі мен көлемі, сондай-ақ Cell Salvage жүйесін пайдалану жиілігі.

Күтілетін нәтижелер. Қазіргі таңда пациенттерді зерттеуге қосу жалғасуда. Карбоксимальтозды темір қолдану инфекциялық асқынулардың жиілігін төмендетіп, аллогендік трансфузияларға қажеттілікті азайтып, пациенттердің қалпына келуін жақсартады деп болжануда.

Кілт сөздер: эндопротездеу; ортопедия; перипротездік буын инфекциясы; қауіп факторлары; операцияға дейінгі терапия; анемия; зерттеу протоколы