Future Oncology

ISSN: 1479-6694 (Print) 1744-8301 (Online) Journal homepage: www.tandfonline.com/journals/ifon20

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To cite this article: Hiroki Yukami, Toshifumi Yamaguchi, Shunji Endo, Shogen Boku, Yukinori Kurokawa, Toshimasa Tsujinaka, Toshio Shimokawa & Taroh Satoh (21 Oct 2025): ASTRON (OGSG 2401) study protocol: Ferric carboxymaltose for iron deficiency anemia in gastrointestinal cancer, Future Oncology, DOI: 10.1080/14796694.2025.2569574

To link to this article: https://doi.org/10.1080/14796694.2025.2569574

FUTURE ONCOLOGY
https://doi.org/10.1080/14796694.2025.2569574

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CLINICAL TRIAL PROTOCOL

ASTRON (OGSG 2401) study protocol: Ferric carboxymaltose for iron deficiency anemia in gastrointestinal cancer

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ABSTRACT

Introduction: Anemia presents a significant challenge in gastrointestinal cancer patients undergoing chemotherapy, adversely affecting qualityof life and treatment continuity. Conventional treatments such as red bloodcell transfusions, erythropoiesis-stimulating agents, and oral iron have limitations, including thrombosis risk, supply constraints,and poor tolerability.

Areas covered: Ferriccarboxymaltose (FCM) IFON_A_2569574 forcontrolled uptake, enabling safe administration of large doses. Thisprospective multicenter study evaluates FCM for managing iron deficiency anemiain patients with unresectable or recurrent gastric or colorectal cancerreceiving chemotherapy. The protocol involves administering 1500 mg of FCM inthree 500 mg doses, each given at least 7 days apart and all within 29 daysfrom the first dose (Day 1). The primary endpoint is the rate of hemoglobinimprovement at 8 weeks. A sample size of 50 patients was calculated to detect a33% improvement rate against a 15% threshold with 80% power.Secondary endpoints include hemoglobin improvement rates at 4 and 12 weeks, andQoL assessment at 4, 8, and 12 weeks.

Expert opinion/commentary: We anticipate thatour findings will support anemia management in this patient population.

Clinicaltrial registration: jRCTs051240288

PLAIN LANGUAGE SUMMARY

Many people with gastric or colorectal cancer who receive chemotherapy develop a condition called iron deficiency anemia (IDA). This can cause fatigue and affect their quality of life and ability to continue treatment. Existing treatments such as blood transfusions, erythropoiesis-stimulating agents, and iron pills have limitations. This study investigates whether a newer type of intravenous iron, called ferric carboxymaltose (FCM), can effectively and safely treat IDA in these patients. We are enrolling approximately 50 patients with advanced gastric or colorectal cancer with IDA while receiving chemotherapy. Participants will receive FCM intravenously. A total dose of 1500 mg of FCM will be administered as three separate doses of 500 mg each. Each dose must be given at intervals of at least 7 days, and all three doses must be completed by Day 29, considering the day of first administration as Day 1. The main goal is to evaluate the extent of improvement in anemia after 8 weeks without the need for a blood transfusion. We will also evaluate changes in their quality of life using standardized questionnaires for people with advanced gastric or colorectal cancer.

ARTICLE HISTORY
Received 29 July 2025
Accepted 29 September 2025

KEYWORDS
gastric cancer; colorectal cancer; iron deficiency anemia; ferric carboxymaltose; gastrointestinal cancer; intravenous iron; cancer-related; chemotherapy

1. Introduction

1.1. Background and rationale

Iron deficiency anemia (IDA) is a common comorbidity in patients with cancer, particularly among those undergoing chemotherapy [1,2]. IDA reduces the quality of life (QoL) and may hinder the continuation of chemotherapy. Current treatments for cancer- and chemotherapy-associated anemia include red blood cell transfusions and erythropoiesis-stimulating agents (ESAs), with or without concurrent iron therapy. Red blood cell transfusions are limited by their dependence on voluntary donation and carry risks such as transfusion-related infections, thrombosis, and immune reactions [3]. Additionally, ESAs are also associated with safety concerns, including an increased risk of thrombosis [4,5]. Regarding iron therapy, a phase III study compared oral iron supplements with conventional intravenous iron (iron sucrose) in patients with IDA receiving chemotherapy without ESAs [6]. Hemoglobin improvement was observed in 23% of patients receiving intravenous iron and in 18% of those receiving oral iron. However, the difference was not statistically significant ($P = 0.45$). Oral iron supplements are further limited by poor gastrointestinal absorption and frequent intolerance [7,8]. In one prior study, adverse events were more common with oral

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Article highlights

Introduction
- Iron deficiency anemia (IDA) is highly prevalent in patients with gastrointestinal cancer receiving chemotherapy, impairing quality of life (QoL) and treatment continuity.
- Standard treatments such as transfusions and erythropoiesis-stimulating agents (ESAs) carry significant risks – transfusions may cause infections, immune reactions, and thrombosis, while ESAs are associated with increased thromboembolic risk and potential adverse impact on survival; oral iron supplementation is limited by poor absorption and tolerability.
- Ferric carboxymaltose (FCM), a newer intravenous iron formulation, enables safe, large-dose administration with fewer infusions and may overcome limitations of existing therapies.

Methods
- The ASTRON study (OGSG 2401) is a multicenter, single-arm, open-label, interventional clinical trial.
- Patients with advanced gastric or colorectal cancer undergoing chemotherapy and diagnosed with IDA (hemoglobin < 10.0 g/dL, transferrin saturation < 20%) are eligible.
- FCM is administered intravenously at a total dose of 1500 mg over three separate administrations within 29 days.
- The primary endpoint is the hemoglobin improvement rate at Week 8 without transfusion; secondary endpoints include hemoglobin improvement at Weeks 4 and 12, and changes in QoL measured by FACT-An and EQ-5D.

Discussion
- FCM monotherapy may offer an effective and safe approach for anemia in gastrointestinal cancer.
- This trial is the first prospective interventional evaluation of FCM specifically in gastrointestinal cancer patients receiving chemotherapy.

Conclusion
- The ASTRON study will provide prospective evidence for FCM as a supportive care strategy in gastrointestinal cancer, aiming to reduce transfusion dependency, avoid ESA use, and enhance QoL-centered anemia management.

iron, and treatment discontinuation due to intolerance occurred more frequently than with intravenous iron [9].

Ferric carboxymaltose (FCM) is a newer intravenous iron formulation developed by Vifor Pharma Inc. (Switzerland). It consists of a polynuclear iron (III)-hydroxide core stabilized by a non-dextran-based carboxymaltose shell. FCM is absorbed by reticuloendothelial cells and gradually releases iron into the serum, minimizing the release of cytotoxic free iron into circulation. This allows the safe administration of large iron doses [10]. Unlike conventional intravenous iron products, FCM enables iron repletion and anemia correction with fewer administrations [8].

In a German observational study involving 639 patients with malignant tumors, hemoglobin improvement without transfusion was similar between patients receiving FCM plus ESAs (n = 46) and those receiving FCM alone (n = 233) [11]. However, the study's non-interventional design limited its rigor: only half of the participants underwent follow-up blood testing, and FCM dosing and timing were not standardized. Additionally, approximately 20% of the cohort was not receiving chemotherapy, limiting the applicability of the findings to chemotherapy-specific settings.

1.2. Objectives

We designed a prospective, multicenter clinical trial to assess the efficacy and safety of FCM in patients with gastrointestinal cancer and IDA receiving chemotherapy without concomitant ESA or transfusion support.

1.3. Trial design

This is a multicenter, single-arm, open-label, specified clinical trial (OGSG 2401) conducted under the Japanese Clinical Trials Act by the Osaka Gastrointestinal Cancer Chemotherapy Study Group. It is designed to confirm the efficacy and safety of FCM in patients with IDA who are receiving chemotherapy for advanced gastric or colorectal cancer. The study design is summarized in Figure 1 The study was registered in the Japan Registry of Clinical Trials (jRCTs051247 March 288, 2024).

2. Methods

2.1. Participants

2.1.1. Eligibility criteria

To be eligible for the trial, patients must meet the following criteria:

(1) Histologically confirmed adenocarcinoma of the stomach or colorectum.
(2) Receiving chemotherapy for unresectable or recurrent disease and expected to continue treatment. Chemotherapy may include cytotoxic agents, molecular targeted agents, or immune checkpoint inhibitors.
(3) Hemoglobin level < 10.0 g/dL.
(4) Transferring saturation (TSAT) < 20%. TSAT is calculated by dividing serum iron by total iron-binding capacity and multiplying by 100.
(5) Age ≥20 years at the time of enrollment.
(6) Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 to 2.
(7) Body weight ≥35 kg.
(8) Capable of oral intake.
(9) Expected to continue chemotherapy for at least 12 weeks following enrollment.
(10) Expected survival time of at least 6 months.
(11) No oral iron supplementation (including over-the-counter products) within 28 days prior to baseline blood sampling.
(12) No administration of intravenous iron, red blood cell transfusions, ESAs, iron chelators, progestins, gonadotropin-releasing hormone (GnRH) agonists/antagonists, or ethisterone derivatives within 56 days prior to baseline blood sampling.
(13) Written informed consent obtained before enrollment in the study.

2.1.2. Exclusion criteria

Patients who meet any of the following criteria are not eligible for the study:

(1) Active bleeding requiring red blood cell transfusion.
(2) Hemoglobin level < 7.0 g/dL.

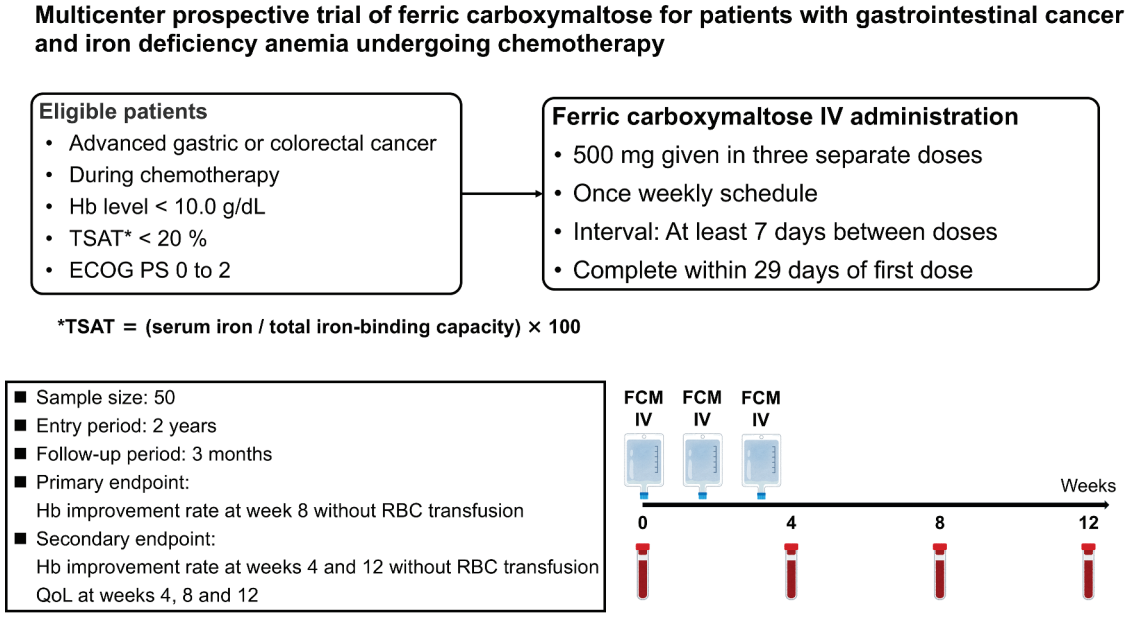

Figure 1. Study schema.

Hb, hemoglobin; TSAT, transferrin saturation; ECOG PS, Eastern Cooperative Oncology Group Performance Status; RBC, red blood cell; FCM, ferric carboxymaltose; IV, intravenous; QoL, quality of life.

(3) Symptomatic brain metastases or leptomeningeal metastases.
(4) Known hematologic disorders such as hematopoietic stem cell dysfunction, globin synthesis abnormalities, increased red blood cell destruction (hemolysis), impaired erythropoiesis, or anemia due to chronic kidney disease.
(5) Active bacterial or fungal infection accompanied by a body temperature of 38°C or higher.
(6) Psychiatric disorders or symptoms that, in the opinion of the investigator, may interfere with study participation.
(7) Considered to require immediate red blood cell transfusion, as judged by the principal investigator or sub-investigator.
(8) Any other condition that the principal investigator or sub-investigator considers inappropriate for study participation.

2.2. Treatment

FCM will be administered intravenously either by slow injection or drip infusion. A total dose of 1500 mg will be delivered as three separate doses of 500 mg. Each dose must be administered at intervals of at least 7 days. All three doses must be completed by Day 29, counting the first administration day as Day 1 (Figure 2). Concomitant administration of FCM and chemotherapy on the same day is permitted.

2.3. Assessment

Blood tests and QoL assessments will be conducted at Weeks 4, 8, and 12. QoL will be evaluated using the Functional Assessment of Cancer Therapy – Anemia (FACT-An) and EQ-5D questionnaires.

The primary endpoint is the hemoglobin improvement rate, defined as the proportion of patients achieving an increase of at least 1 g/dL from baseline at Week 8 without red blood cell transfusion. Secondary endpoints include hemoglobin improvement rate at Weeks 4 and 12 relative to baseline, and changes from baseline in FACT-An and EQ-5D scores at Weeks 4, 8, and 12. Clinically meaningful improvement in QoL will be defined according to the established minimal clinically important difference for the FACT-An and EQ-5D instrument. Exploratory subgroup analyses will be conducted based on baseline iron parameters and relevant clinical factors to account for heterogeneous causes of anemia. However, these analyses will be exploratory in nature and statistical power will be limited. Missing data will be reported, and sensitivity analysis will be performed to assess the robustness of the findings.

2.4. Sample size calculation

The threshold for hemoglobin improvement rate at 8 weeks following initial administration in anemic patients undergoing chemotherapy was set at 18%, based on findings reported by Vanita et al. [6] We hypothesized that if the current treatment protocol exceeded this threshold by approximately 15%, it would represent a clinically meaningful improvement, resulting in an expected response rate of 33% at 8 weeks.

To test this hypothesis against the null hypothesis H_0 that the hemoglobin improvement rate is 18%, we used a one-sided significance level of 5% and 80% power. Based on an exact test for a binomial proportion, we calculated that a minimum of 47 patients would be required. Allowing for

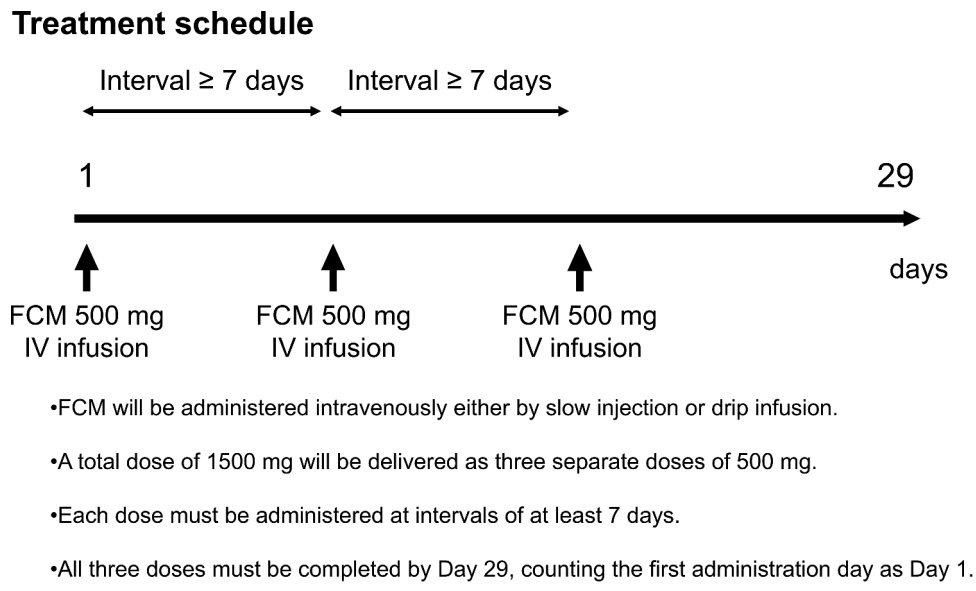

Figure 2. Treatment schedule.
FCM, ferric carboxymaltose; IV, intravenous.

potential dropouts and ineligible cases, the final target sample size was set at 50 patients.

3. Ethics & dissemination

This prospective interventional trial will be conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was granted by the Clinical Research Board of Osaka Medical and Pharmaceutical University Hospital (Approval Number: CRB24-12). Participants will be provided with detailed information about the trial both verbally and in writing, and written informed consent will be obtained prior to enrollment.

The results of this trial will be disseminated through peer-reviewed publications and presentations atscientific meetings. In addition, the findings may, when appropriate, be shared with patient advocacy groups and relevant clinical practice guideline committees to facilitate broader communication and potential implementation in clinical practice.

4. Discussion

IDA is a common comorbidity in patients with various cancers, particularly those receiving chemotherapy [1,2] It has been reported that more than 50% of patients undergoing cancer chemotherapy develop anemia [1]. The negative impact of anemia on physical performance and survival is well documented, underscoring the importance of effective management [12]. The National Comprehensive Cancer Network guidelines recommend considering intravenous or oral iron supplementation for absolute iron deficiency (serum ferritin < 30 ng/mL and transferrin saturation < 20%); however, oral iron is often limited by poor absorption and gastrointestinal intolerance, leading to treatment discontinuation [7,13]. The European Society for Medical Oncology guidelines recommend ESAs and newer intravenous iron formulations, such as FCM, for functional IDA defined as TSAT < 20%. Nevertheless, growing evidence suggests that aggressive ESA use may increase mortality; therefore, minimizing ESA exposure is preferable [14]. Previous studies have suggested that in patients with IDA, FCM monotherapy without ESAs may offer efficacy comparable to FCM combined with ESA therapy [11].

Red blood cell transfusion remains a treatment option but relies on voluntary blood donation and carries risks, including infection and immune reactions. Thus, reducing transfusion dependency is clinically important. Accordingly, the primary endpoint of the present trial was the hemoglobin improvement rate following FCM monotherapy without concurrent ESA administration or red blood cell transfusion. In addition, QoL is assessed using validated instruments, with particular attention to capturing symptoms closely related to anemia, such as fatigue, thereby providing a patient-centered evaluation of treatment benefits.

In gastrointestinal cancer, anemia may result not only from chemotherapy-induced myelosuppression but also from chronic bleeding at the primary tumor site. Moreover, owing to the nature of gastrointestinal cancer, patients commonly experience gastrointestinal symptoms such as nausea, which often interfere with the feasibility of oral iron supplementation. Considering these clinical characteristics, FCM allows consistent administration and may represent an appropriate therapeutic option for anemia in patients with gastrointestinal cancer receiving chemotherapy. FCM monotherapy is expected to improve hemoglobin levels in these patients without the need for ESA therapy or transfusions. To the best of our knowledge, no prospective interventional clinical trial has been conducted to evaluate FCM specifically in patients with gastrointestinal cancer undergoing chemotherapy. Therefore we conduct a multicenter prospective trial to evaluate the efficacy of FCM in this setting. While the single-arm design of the trial represents a limitation, conventional oral iron therapy has generally not demonstrated sufficient efficacy in

this population. We thus adopt a single-arm design. The results of this study will contribute to establishing supportive care strategies for anemia management in patients with gastrointestinal cancer.

5. Conclusion

The ASTRON study (OGSG 2401) will be the first multicenter, prospective, interventional study to evaluate FCM for iron deficiency anemia in patients with advanced gastric or colorectal cancer receiving chemotherapy. By assessing the efficacy and safety of FCM without concomitant ESAs or red blood cell transfusion support, this study aims to establish a patient-centered approach to anemia management in this population. The inclusion of QoL assessments will further clarify clinical benefits beyond hematologic improvement. The findings of this trial are expected to support safe and effective anemia management strategies, reduce transfusion dependency, and optimize supportive care in gastrointestinal cancer.

Funding

This work was supported by the AstraZeneca; Bristol-Myers Squibb; Chugai Pharmaceutical; Eisai; Ono Pharmaceutical; Zeria Pharmaceutical Co., Ltd; Merck-Biopharm; Daiichi-Sankyo; from MSD; Shionogi; Taiho Pharmaceutical; Yakult Honsha.

Author contributions

Hiroki Yukami: Writing – originaldraft; Methodology; Project administration. Toshifumi Yamaguchi:Writing – review & editing; Methodology; Conceptualization;Project administration. Shunji Endo: Writing – review &editing; Methodology. Shogen Boku: Writing – review & editing; Methodology. Yukinori Kurokawa: Writing – review & editing; Methodology. Toshimasa Tsujinaka: Writing – review & editing; Methodology. Toshio Shimokawa: Writing – review & editing; Methodology; Supervision. Taroh Satoh: Writing – review &editing; Methodology; Supervision.

Financial disclosure statement

This clinical trial was funded by Zeria Pharmaceutical Co., Ltd. The company also supplied the drug used in this study (ferric carboxymaltose). The funder had no role in the study design; data collection, data analysis and interpretation; or the decision to submit results for presentation or publication. No investigators have received honoraria or advisory fees from the funder. This study was supported by Osaka Gastrointestinal cancer chemotherapy Study Group (OGSG).

Disclosure statement

Hiroki Yukami has no competing interests to disclose. Toshifumi Yamaguchi has no competing interests to disclose. Shunji Endo reports personal fees from Ono-Pharmaceutical, Bristol-Myers-Squib, and MSD. Shogen Boku reports receiving honoraria from MSD, Ono-Pharmaceutical, Chugai-Pharmaceutical, and Bristol-Myers-Squib. Yukinori Kurokawa received lecture fees from Taiho Pharmaceutical, Ono Pharmaceutical, Bristol Myers Squibb, Astellas Pharma, Daiichi Sankyo, and MSD, and research grants from Taiho Pharmaceutical and Yakult Honsha. Toshimasa Tsujinaka has no competing interests to disclose. Toshio Shimokawa has no competing interests to disclose. Taroh Satoh reports grants and personal fees from Ono-Pharmaceutical, grants and personal fees from Bristol-Myers-Squib, personal fees from BeiGene, grants and personal fees from Daiichi-Sankyo, grants and personal fees from MSD, grants and personal fees from Astra-Zeneca, grants and personal fees from Chugai-Pharmaceutical, grants and personal fees from Merck-Biopharm, grants from Shionogi, grants from Eisai, grants and personal fees from Taiho-Pharmaceutical.

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval (the Clinical Research Board of Osaka Medical and Pharmaceutical University Hospital (Approval Number: CRB24-12)) and/or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Writing disclosure

Medical writing support was provided by Editage and was funded by Zeria Pharmaceutical Co., Ltd.

Geolocation information

This study was conducted at multiple clinical sites in Japan.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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