

Study on how a new iron supplement is absorbed in women when taken in multiple doses

Submission date 25/02/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/03/2026	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/06/2026	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In previous in-vitro studies, the product showed high iron bioaccessibility (95.99%) after simulated gastrointestinal digestion, and near-complete transepithelial iron permeation ($98.87 \pm 4.39\%$) after 4 hours in a validated intestinal cell model. The product also demonstrated good intestinal tolerability across a wide range of tested concentrations, along with antioxidant properties that may help reduce oxidative stress related to iron supplementation. These preclinical data provide a rationale for the clinical investigation as a well-tolerated and highly bioavailable oral iron formulation.

The aim of the study is to evaluate the bioavailability (i.e., the amount of iron that reaches the bloodstream) of a new iron-based dietary supplement formulation after single and multiple oral administration.

The study will also assess the safety and tolerability of the investigational product, as well as participants' satisfaction with its intake.

Who can participate?

Healthy adult women, aged 18-60 years old inclusive, and those with mild iron deficiency .

What does the study involve?

The investigational product (i.e., one capsule of Monurelle® Ferro Naturale) will be administered once a day for 3 consecutive days. The investigational product will be orally administered in the morning, at $08:00 \pm 1$ h, under fasting conditions, from Day 1 to Day 3. It will be swallowed (without chewing) by study participants with 150 mL of still mineral water at room temperature.

What are the possible benefits and risks of participating?

Participation in the study is not expected to provide any direct benefit; however, it may contribute to generating additional information on the investigational product that could be useful for future patients. Participants may indirectly benefit from the medical assessments performed free of charge during the course of the study. This is the first clinical study of this new iron formulation; therefore, specific safety and tolerability data in humans are not yet available. However, oral iron supplements are generally well tolerated when taken at

appropriate doses. Given the low dosage administered in this study (30 mg once daily for three consecutive days), no particular risks are expected. Possible side effects may include metallic taste, gastrointestinal discomfort, constipation, diarrhea, nausea, and vomiting.

Where is the study run from?

The study was conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo (Switzerland)

When is the study starting and how long is it expected to run for?

February 2026 to May 2026

Who is funding the study?

Zambon S.p.A., Italy

Who is the main contact?

Dr Milko Radicioni, clinic@croalliance.com

Contact information

Type(s)

Public, Scientific

Contact name

Dr Pietro Magrone

ORCID ID

<https://orcid.org/0009-0002-9829-1477>

Contact details

Via Lillo del Duca, 10

Bresso (MI)

Italy

20091

+39.346.26.42.844

pietro.magrone@zambongroup.com

Type(s)

Scientific, Principal investigator

Contact name

Dr Milko Radicioni

ORCID ID

<https://orcid.org/0000-0002-3940-8375>

Contact details

Via F.A. Giorgioli, 14

Arzo

Switzerland

Additional identifiers

Study information

Scientific Title

Bioavailability study of a new iron supplement formulation administered as multiple doses to women single centre, multiple-dose, single-way, open-label, bioavailability study

Study objectives

The primary objective of the study is to investigate the bioavailability of the iron in serum after single and multiple oral administrations of Monurelle® Ferro Naturale formulation in healthy or with mild iron deficiency women.

The secondary objectives of the study are:

- Subjective evaluation of the product intake and participant's satisfaction
- To evaluate safety and tolerability of the investigational product.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 28/01/2026, Comitato etico cantonale (c/o Ufficio di sanità Via Orico 5, Bellinzona, 6501, Switzerland; +41 91 814 30 57; dss-ce@ti.ch), ref: 2025-02618; Ref. CE 5043

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Basic science, Supportive care, Bioavailability evaluation of a new iron supplement formulation

Study type(s)

Health condition(s) or problem(s) studied

The study population will include 14 healthy or with mild iron deficiency women

Interventions

The investigational product (i.e., one capsule of Monurelle® Ferro Naturale) will be administered once a day for 3 consecutive days. The investigational product will be orally administered in the morning, at 08:00±1 h, under fasting conditions, from Day 1 to Day 3. It will be swallowed (without chewing) by study participants with 150 mL of still mineral water at room temperature.

Intervention Type

Supplement

Primary outcome(s)

1. Pharmacokinetic (PK) parameters baselinecorrected serum iron concentrations, including maximum concentration (C_{max}), time to reach C_{max} (t_{max}), terminal elimination rate constant (λ_z), half-life ($t_{1/2} = \ln 2 / \lambda_z$), area under the curve from time zero to the last measurable concentration (AUC_{0–t}), area under the curve extrapolated to infinity (AUC_{0–∞}), and the percentage of extrapolated AUC (%AUC_{extra}), measured using Phoenix WinNonlin™ PK analysis at pre-dose (0) and 1, 2, 3, 4, 5, 8 h post-dose

Key secondary outcome(s)

1. Product intake global evaluation and participant's satisfaction measured using a short questionnaire at 3 h after each intake, from Day 1 to Day 3

2. Safety and tolerability, measured using adverse events recording, vital signs (blood pressure, heart rate), physical examinations, body weight, laboratory parameters and gastrointestinal tolerability, at screening and final visit for vital signs (blood pressure, heart rate), physical examinations, body weight, and laboratory parameters. Gastrointestinal tolerability will be assessed at day 1, 2 and 3. Adverse Events at all study visits.

Completion date

01/03/2026

Eligibility

Key inclusion criteria

1. Informed consent: Written informed consent signed before study inclusion.
2. Sex and age: Women aged 18–60 years (inclusive).
3. BMI: Between 18.5 and 30 kg/m² (inclusive).
4. Vital signs: Systolic blood pressure 100–139 mmHg, diastolic blood pressure 50–89 mmHg, heart rate 50–99 bpm, measured after 5 minutes of seated rest.
5. Understanding and compliance: Ability to understand the nature, purpose, risks, and requirements of the study and to comply with all study procedures.
6. Serum iron: Between 4.0 and 12.0 µmol/L at screening.
7. Menstrual cycle: Women of childbearing potential must be in days 5–20 of their menstrual cycle during the interventional phase and must not have metrorrhagia.
8. Contraception and fertility:
 - 8.1. Women of childbearing potential must use a reliable contraceptive method for at least 2 months prior to screening (hormonal methods, non-hormonal IUD, or barrier methods with spermicide), or have a sterile partner or a partner using a condom with spermicide. True abstinence is acceptable if consistent with the woman's usual lifestyle.
 - 8.2. Natural methods, lactational amenorrhea, and withdrawal are not acceptable.

8.3. Women who are not of childbearing potential or who have been postmenopausal for at least 1 year are eligible.

8.4. A negative pregnancy test is required at screening and on Day -1 for all participants.

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Female

Total final enrolment

12

Key exclusion criteria

1. ECG: Clinically significant abnormalities on 12-lead ECG (supine position).
2. Physical examination: Clinically significant abnormal findings that, in the Investigator's opinion, may interfere with the study objectives.
3. Laboratory tests: Clinically significant abnormal laboratory values indicating illness, particularly abnormal ferritin and/or CRP levels suggesting ongoing inflammation, that may affect study outcomes.
4. Allergy: Known or suspected hypersensitivity to study product ingredients; history of anaphylaxis to drugs or supplements, or significant allergic reactions that may impact the study.
5. Medical history: Significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, dermatological, hematological, endocrine, or neurological diseases that may interfere with the study.
6. Medications: Use of medications (including OTC drugs, herbal products, and nutritional supplements, especially iron supplements) within 2 weeks before study start that may affect study outcomes. Hormonal contraceptives are permitted.
7. Other clinical studies: Participation in another investigational product or device study within the previous 3 months (calculated from the first day of the month following the last visit of the previous study to the first day of the current study).
8. Blood donation: Blood donation within 3 months prior to the study.
9. Substance use: History (within the past 12 months) of drug abuse, alcohol consumption >1 drink/day, caffeine intake >5 cups of coffee/tea per day, or tobacco use ≥10 cigarettes/e-cigarettes per day.
10. Drug screening: Positive urine drug test at screening or Day -1.
11. Alcohol test: Positive alcohol test at screening or Day -1.
12. Diet: Abnormal diet (<1600 or >3500 kcal/day), significant dietary changes within 4 weeks prior to the study, or vegetarian diet.
13. Pregnancy/lactation: Positive or missing pregnancy test at screening or Day -1, or women who are pregnant or breastfeeding.

Date of first enrolment

17/02/2026

Date of final enrolment

27/02/2026

Locations

Countries of recruitment

Switzerland

Sponsor information

Organisation

Zambon (Italy)

ROR

<https://ror.org/04zzq8d03>

Funder(s)

Funder type**Funder Name**

Zambon Italia

Alternative Name(s)

Zambon Pharma, Zambon Italia Srl

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		22/04/2026	22/04/2026	No	No
Plain English results		24/06/2026	24/06/2026	No	Yes