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Comparative study between Iron supplements: a new, patented, sublingual formulation of Iron Citrate versus SiderAL Forte® capsule, to compare the rate and extent of iron absorption after single dose administration in healthy male volunteers

Submission date
22/01/2016

Recruitment status
No longer recruiting

Registration date
05/02/2016

Overall study status
Completed

Last Edited
05/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Iron deficiency anaemia is a condition where a lack of iron leads to a fewer than normal number of red blood cells. This can lead to less than normal amounts of oxygen being supplied to the organs and tissues in the body. Common symptoms include feeling tired, feeling breathless, heart palpitations and looking very pale. Treatment involves taking iron supplements to increase the amount of iron in the body. Taking iron supplements, however can cause a number of side effects including abdominal pain, constipation and diarrhoea. Sublingual administration, that is placing medication under the tongue to be absorbed, should ensure that the iron is rapidly taken up by the body while avoiding the side effects typically associated with taking iron tablets. The aim of this study was to compare the bioavailability (i.e. the amount of product that reaches the circulation) of the iron, when taken orally (using the commercial product Sideral Forte®) compared to when absorbed under the tongue.

Who can participate?
Healthy adult (18-55) volunteers

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 take a single dose of the oral iron supplement. Those in group 2 take a single dose of the sublingual supplement. One week later all participants are given the other type of supplement to take. Blood samples are taken before and after each iron supplement is taken. These blood samples are then analysed to measure the amount of iron they contain.

What are the possible benefits and risks of participating?
No risks and no substantial benefits are associated to a single dose of iron supplements.

Where is the study run from?
CROSS Research S.A (Switzerland)

When is the study starting and how long is it expected to run for?
June 2015 to January 2016

Who is funding the study?
Biofer S.p.A. (Italy)

Who is the main contact?
1. Dr Alessandro Lapini Sacchetti (public)
2. Dr Stefania Morandi (scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRO-PK-15-298 - Sponsor Code B137

Study information

Scientific Title
Pilot comparative bioavailability study of sublingual administration of Iron Citrate versus SiderAL Forte® in healthy male volunteers

Study objectives
Sublingual administration is more direct than oral administration because the product enters the venous circulation, avoiding the passage through the gastrointestinal tract, with the double advantage of minimising the inter-subject variability associated with the digestion process and eliminating the adverse effects associated with the passage through the gastrointestinal tract. The present exploratory study was aimed to investigate the pharmacokinetic (PK) profile of the test (T) nutraceutical product sublingual iron citrate, sachets containing 30 mg of Fe2+, vs. the reference (R) nutraceutical commercial product, capsules containing 30 mg of Fe2+.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitato Etico Cantonale, Canton Ticino, Switzerland, 24/09/2015, ref: CE2943

Study design
Interventional, single centre, single dose, randomised, open-label, two-period, cross-over pilot study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Iron deficiency

Interventions
A single oral dose of 30 mg of iron, i.e. one sachet of test product (T) and one capsule of reference product (R), was administered to healthy male volunteers under fasting conditions in

two consecutive study periods with a wash-out interval of at least 7 days between the two administrations.

Intervention Type
Supplement

Primary outcome measure
Rate (Cmax) and extent (AUC0-t) of iron absorption after single dose administration of test and reference products.

Eight blood samples were drawn from each study subject 24h, 12h and 0h before and 1h, 2h, 3h, 5h and 8h after the administration of 30 mg of Fe2+ as test and reference products. Samples were analyzed in order to assess serum levels of iron at each time-point and descriptive statistics of these parameters (Both mean+SD and individual responses) were used as outcome measures.

Secondary outcome measures
1. Ferritin and transferrin levels after single dose administration of T and R; safety and tolerability data. Eight blood samples were drawn from each study subject 24h, 12h and 0h before and 1h, 2h, 3h, 5h and 8h after the administration of 30 mg of Fe2+ as test and reference products. Samples were analyzed in order to assess serum levels of ferritin and transferrin at each time-point and descriptive statistics of these parameters (Both mean+SD and individual responses) were used as outcome measures.
2. Safety and general tolerability of the drug, based on the following assessments:
2.1. AEs throughout the study, from informed consent up to the final visit/ETV
2.2. Vital signs were measured, at screening, on day 1 of each study period at pre-dose and 4 h post-dose, and at final visit
2.3. Physical examination was performed at screening and at final visit. Body weight (BW) was recorded at screening and at final visit/ETV.
3. Organoleptic and ease of use characteristics of test formulation assessment were evaluated by the subjects through a specific questionnaire prepared for the study. Laboratory analysis were performed at screening and at final visit.

Overall study start date
24/06/2015

Completion date
20/01/2016

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and Age: males, 18-55 years old inclusive
3. Body Mass Index (BMI): 18.5-30 kg/m2 inclusive
4. Vital signs: systolic blood pressure (SBP) 100-139 mmHg, diastolic blood pressure (DBP) 50-89 mmHg, heart rate (HR) 50-90 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study

Participant type(s)

Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Male

Target number of participants
7

Key exclusion criteria
Electrocardiogram (ECG) 12-leads (supine position): clinically significant abnormalities
2. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
4. Allergy: ascertained or presumptive hypersensitivity to the investigated nutritional product (iron) and/or formulations' ingredients (e.g. vitamin C); history of anaphylaxis to drugs, nutritional supplements or allergic reactions in general, which the investigator considered could affect the outcome of the study
5. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that could interfere with the aim of the study
6. Medications: medications, including over the counter (OTC) medications, herbal remedies and nutritional supplements for 2 weeks before the start of the study

Date of first enrolment
30/09/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Switzerland

Study participating centre
CROSS Research S.A
Phase I Unit
Via F.A. Giorgioli 14
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Switzerland
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Sponsor information

Organisation
Biofer S.p.A.

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Biofer S.p.A. (Italy)

Results and Publications

Publication and dissemination plan
Biofer intends to disseminate the outcomes of this trial to doctors in medical congresses and meetings regarding anemia and other iron deficiency related conditions, starting from April 2016.

Intention to publish date
30/04/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available