Patient information and consent form

for participation in the clinical study

Pilot study to obtain preliminary evidence on the influence of three months of oral intake of a high bioavailability iron supplement (OLEOvital® EISEN FORTE) on hemoglobin concentrations in whole blood donors with iron deficiency.

NCT04250298

Original Version 1.3 of 10/01/2019

Translated Version 1.4 of 02/19/2023

Patient information and consent form

for participation in the clinical study

Pilot study to obtain preliminary evidence on the influence of three months of oral intake of a high bioavailability iron supplement (OLEOvital® EISEN FORTE) on hemoglobin concentrations in whole blood donors with iron deficiency.

Short description:

Study on sucrosomal iron supplementation in blood donors.

Dear blood donor!

We invite you to participate in the clinical study mentioned above. You will be informed about this in a detailed medical consultation.

Your participation in this study is voluntary. You may withdraw from the study at any time without giving reasons. Refusal to participate or early withdrawal from this study will not adversely affect your medical care.

Clinical trials are necessary to obtain reliable new medical research results. However, an indispensable prerequisite for conducting a clinical trial is that you give your written consent to participate in this clinical trial. Please read the following text carefully as a supplement to the informational interview with your physician and do not hesitate to ask questions.

This clinical study is designated as a pilot study.

A pilot study is a smaller study of a few participants with the purpose of being able to assess methods and procedures for a later, larger study. The purpose of this pilot study is to assess the feasibility and efficacy of a possible follow-up study on the administration of the dietary supplement OLEOvital® EISEN FORTE to blood donors. The efficacy will be determined by the hemoglobin and iron storage levels after the end of the intake of OLEOvital® EISEN FORTE.

Please sign the informed consent form only

- if you fully understand the nature and procedure of the clinical study,

- if you are willing to agree to participate, and

- if you are aware of your rights as a participant in this clinical study.

This clinical study, as well as the patient information and consent form, has received a favorable opinion from the responsible ethics committee.

1 What is the purpose of the clinical study?

The purpose of this clinical study is to examine to what extent a three-month intake of the iron-containing food supplement OLEOvital® EISEN FORTE has an effect on the hemoglobin value and the iron storage value (ferritin) of blood donors. We are particularly interested in how strong the effects on the above blood values are, how well the supplement is accepted and how well it is tolerated. These data should help us to obtain initial data for a larger-scale study.

2 What other treatment options are available?

In Austria, various iron preparations (e.g. ferrous sulfate, ferrous fumarate, ferrous gluconate) in tablet or capsule form are commonly used for the treatment of iron deficiency or anemia.

Another option for the treatment of iron deficiency is the administration of iron infusions (e.g. ferric carboxymaltose).

3) How does the clinical study work?

This clinical trial will be conducted at the University Department of Blood Group Serology and Tranfusion Medicine in Graz, and a total of 50 people will participate.

Your participation in this clinical trial is expected to last 90-120 days.

As part of a blood donation campaign, you were deferred from donating blood due to a hemoglobin level that was too low. You were selected as a possible participant in this study because your blood was also found to have a low iron storage level during routine testing at our clinic.

The following procedures will be performed for study purposes only:

On the occasion of this clinical study you are asked to come to the outpatient clinic of the Univ. Clinic for Blood Group Serology and Transfusion Medicine of the LKH Graz. A total of two visits are necessary. On the occasion of the first visit, you will be informed in a medical consultation and you will be asked to give your written consent. Furthermore, we ask you to fill out a questionnaire. At this visit, you will also be given the iron-containing dietary supplement to take home with appropriate instructions. At a second visit after at least 90 days, but no more than 120 days, which will also take place at our clinic, we will take two blood samples from you and you will again be asked to fill out a questionnaire.

You will be informed by us in writing about your values and, if necessary, we will recommend further measures in this context.

Adherence to the visit schedule, including the study physician's instructions, is critical to the success of this clinical trial.

4 What is the benefit of participating in the Clinical Study?

Taking OLEOvital® IRON FORTE may prevent the development of anemia resulting from iron deficiency. Symptoms that may be caused by iron deficiency (fatigue, concentration problems, headaches, dizziness, sleep disorders and depressive mood) may be eliminated.

However, you may not receive any direct health benefit from your participation in this clinical trial.

5. Are there any risks, discomforts, or side effects?

There may be discomfort or even risks associated with the procedures performed as part of this clinical trial. For example, very rarely, temporary complications such as pain, circulatory problems or a bruise may occur during the blood collection procedure. Extremely rarely, injury to a cutaneous nerve may occur during blood collection.

No side effects have been described for the intake of OLEOvital® EISEN FORTE.

6. additional intake of medicaments?

During the entire study period, with the exception of the test product (OLEOvital® EISEN FORTE), the intake of drugs, foodstuffs or dietary foodstuffs to improve the body's iron balance or the use of blood

preserves as well as other preparations to increase red blood cells (erythropoietin) should be avoided as far as possible.

There are no further restrictions regarding the intake of medications.

Does participation in the clinical study have any other effects on lifestyle and what obligations arise from this?

Participation in the clinical study will result in two outpatient visits to the University Clinic Graz. During the study period (i.e. between the first and second visit to our clinic and while taking the dietary supplement), you are not allowed to give a whole blood donation, plasma donation or platelet donation, because you already have an iron deficiency and a blood donation would lead to further iron loss, which could falsify the final results after taking the iron supplement.

Apart from taking the iron supplement and the two outpatient visits to our clinic, there are no other obligations for you.

8) What to do in case of symptoms, side effects and/or injuries?

If any symptoms, concomitants or injuries occur during the course of the clinical study, you must report them to your physician; in the case of serious concomitants, you must report them immediately, by telephone if necessary (see below for telephone numbers, etc.).

9 When will the clinical study be terminated prematurely?

You can revoke your willingness to participate and withdraw from the clinical study at any time, even without giving reasons, without any disadvantages for your further medical care.

Your study doctor will inform you immediately about any new findings that become known in relation to this clinical study and that could become significant for you. On this basis, you may then reconsider your decision to continue participation in this clinical trial.

However, it is also possible that your study doctor may decide to terminate your participation in the clinical trial early without first obtaining your consent. The reasons for this may be:

(a) you cannot meet the requirements of the clinical trial;

b) Your study physician feels that continued participation in the clinical trial is not in your best interest;

If you decide to withdraw early from the clinical trial, or if your participation is terminated early for any of the above reasons, it is important for your own safety that you undergo a normal follow-up examination. This usually consists of a physical examination as well as laboratory tests.

Data protection

With regard to the data collected about you in the course of this clinical study, a fundamental distinction must be made between

1) those personal data by which you are directly identifiable (e.g. name, date of birth, address...),

2) pseudonymized (encrypted) personal data, in which all information that allows direct conclusions to be drawn about your identity is replaced by a code (e.g. a number) or (e.g. in the case of image

recordings) made unrecognizable. The effect of this is that the data can no longer be assigned to your person without the addition of additional information and without disproportionate effort, and

3) anonymized data, where it is no longer possible to trace the data back to your person.

The code is strictly separated from the encrypted data records and is only kept at your study center.

Access to your non-encrypted data will be given to the study physician and other study center staff involved in the clinical trial or your medical care. The data is protected against unauthorized access. In addition, authorized representatives of the sponsor, Prof. Dr. Peter Schlenke, who are bound to secrecy, as well as representatives of domestic and/or foreign health authorities and ethics committees responsible in each case may inspect the non-encrypted data, insofar as this is necessary or prescribed for checking the proper conduct of the clinical study. These persons are subject to a strict duty of confidentiality.

Data will only be passed on in encrypted form. Only encrypted data will also be used for any publications.

All persons who have access to your encrypted and non-encrypted data are subject to the Data Protection Regulation (DSGVO) and the Austrian adaptation regulations in the currently valid version when handling the data.

In the context of this clinical study, no transfer of data to countries outside the EU is intended.

You may revoke your consent to the collection of your data at any time. After your revocation, no further data will be collected about you. However, the data collected until revocation may continue to be used in the context of this clinical study.

Based on legal requirements, you also have the right, provided this does not interfere with the conduct of the clinical trial, to inspect the data collected from you and to have it corrected if you discover any errors.

You also have the right to lodge a complaint with the Austrian data protection authority about the handling of your data (www.dsb.gv.at).

All persons who have access to your encrypted and non-encrypted data are subject to the Austrian Data Protection Act as amended and the General Data Protection Regulation (DSGVO) when handling the data.

The expected duration of the clinical study is one year. The duration of the storage of your data beyond the end of the clinical study is regulated by legal provisions.

If you have any questions about the handling of your data in this clinical study, please contact your study physician first. If necessary, he/she can forward your request to the persons responsible for data protection at the study center.

The data protection officers can be reached at

datenschutz@medunigraz.at (Medical University of Graz)

as well as

datenschutz@kages.at (KAGes)

Are there any costs for the participants? Is there any reimbursement of costs or compensation?

There are no additional costs for you due to your participation in this clinical study. No compensation is provided. In addition to the handing out of the study preparation, an exit ticket for the parking lots of one of the underground garages of the LKH Univ.-Klinikum Graz or alternatively a day ticket of the public transport Graz Zone 101 will be issued.

12. study support

The company Fresenius Kabi Austria GmbH, Graz, partially supports the performance of this study by providing the test products (OLEOVital® Eisen Forte) free of charge. Furthermore, it will pay for assistance in the preparation of the study documents by a professional. Any influence on the study design, the processing of the data, the interpretation of the results or the planned publication is excluded. A financial contribution is not provided to the Medical University of Graz by the company.

12. opportunity to discuss further questions.

If you have any further questions related to this clinical trial, your study physician and his or her staff will be happy to answer them. They will also be happy to answer questions regarding your rights as a patient and participant in this clinical trial. As soon as general results of this clinical study are available, you can also be informed about them if you wish.

A permanent accessibility is given by the duty physician of the University Department of Blood Group Serology and Transfusion Medicine (0316-385-83066).

Name of contact person: Dr. Camilla Drexler

Reachable under: 0316-385-83066

Name of contact person: Dr. Petra Krakowitzky

Available at: 0316- 385 -82032

Name of contact person: Dr. Patrick Torreiter

Available at: 0316 -385 -31139

13) Where can I obtain further information?

You can also obtain further information from the independent and instruction-free patient representation of the province of Styria. DGKS Mag. Renate Skledar, Office of the Styrian Provincial Government

Friedrichgasse 9, 8010 Graz

Tel: (0316) 877-3350 or -3318

Fax: (0316) 877-4823

Mail: ppo@stmk.gv.at http://www.patientenvertretung.steiermark.at/

Should other treating physicians be informed about the participation in the clinical study?

Your primary care physician should be informed of your participation in the clinical trial during your next presentation for completeness.

14. consent form

Name of Participant:

Date Born:

I agree to participate in the clinical trial of sucrosomal iron supplementation in blood donors.

I have been informed by Mr/Mrs ..... in a detailed and comprehensible manner about the clinical study, possible burdens and risks, as well as about the nature, significance and scope of the clinical study, requirements resulting from it for me. I have also read the text of this patient information and consent form, which comprises a total of 8 pages. Any questions that arose were answered by the study physician in a comprehensible and sufficient manner. I have had sufficient time to decide. I have no further questions at this time.

I will comply with the medical orders required for the conduct of the clinical study, but I reserve the right to terminate my voluntary participation at any time without any disadvantages for my further medical care.

I expressly consent to the use of my data collected as part of this clinical trial as described in the "Privacy" section of this document.

I have received a copy of this patient information and consent form. The original will remain with the study physician.

.....

(Date and signature of patient)

.....

(Date, name and signature of the responsible study physician)

(The patient will receive a signed copy of the patient information and consent form; the original will remain in the study physician's folder).