A confirmatory, prospective, open-label, single-arm, reader-blinded multi-centre phase 3 study to assess the diagnostic accuracy of Ferumoxtran-10-enhanced Magnetic Resonance Imaging (MRI) and unenhanced MRI in reference to histopathology in newly-diagnosed prostate cancer (PCA) patients, scheduled for radical prostatectomy (RP) with extended pelvic lymph node dissection (ePLND)

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Primary Objectives1. To confirm superiority of Ferrotran®-enhanced MRI over unenhanced MRI in sensitivity to detect metastases in normal size pelvic lymph nodes in using histopathology after lymph node dissection as established reference method (...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON52732

Source
ToetsingOnline

Brief title
Prostaprogress

Condition

- Metastases

Synonym
Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Saving Patients' Lives Medical B.V. (SPL Medical)
Source(s) of monetary or material Support: SPL Medical

Intervention

Keyword: Diagnostic, ePLND (extended pelvic lymph node dissection), Ferumoxtran-10-enhanced MRI, Prostate cancer

Outcome measures

Primary outcome

The co-primary endpoints for this study will be the observed sensitivity (Se)

and specificity (Sp) of the Ferrotran®-enhanced MRI compared with the

unenhanced baseline MRI in assessing the nodal status (metastatic /

non-metastatic) of the patient with respect to the lymph nodes considered for

lymphadenectomy.

Specificity and sensitivity of Ferrotran®-enhanced and un-enhanced MRI will be

obtained by comparison of each method to histopathology results, and not by

direct comparison of the MRI methods with each other.

The patient will be considered metastatic (patientpositive) if at least one

lymph node is diagnosed as metastatic in histopathology.

Secondary outcome

Secondary endpoints:

Secondary efficacy endpoints:

a) The number and regions of lymph node metastases present in the follow-up MRI in comparison to pre-surgery MRI (unenhanced and Ferrotran®-enhanced).

b) Patients with additional dissection of lymph nodes outside the defined 8 pelvic regions due to Ferrotran® uptake i.e. pre-sacral, peri-rectal, para-aortic, which are not the standard of ePLND.

The secondary efficacy endpoints will be assessed on the basis of the secondary efficacy variables as described below.

Endpoint for patient management

Impact of Ferrotran®-enhanced MRI on patient management

Endpoints for safety and tolerability

Frequency of occurrence and severity of abnormal findings in safety investigations (physical examination, vital signs, 12 lead ECG, clinical laboratory, AEs, concomitant medication) after a single slow drip Ferrotran® infusion.

The assessment of safety and tolerability endpoints will be based on secondary safety and tolerability variables as described below.

Exploratory endpoints:

Qualitative assessment of

• Vessel visibility

• Image quality

Study description

Background summary

The treatment strategy in most cases of cancers is dependent on the staging of the patient*s cancer according to the TNM (tumour-node-metastases) classification. A reduction of cancer mortality could be obtained with appropriate prevention, better and earlier diagnosis and therapeutic progress induced by a better tool.
Detection of lymph node metastases is very important for correctly assessing prognosis and planned therapy in patients with pelvic cancers. Computed tomography (CT) and magnetic resonance imaging (MRI) are used to identify the lymph nodes but the diagnosis is then based on criteria of size and shape of the nodes and these are not specific enough to discriminate between metastatic and non-metastatic lymph nodes. Particularly, normal size lymph nodes with metastatic involvement are frequently not detected and enlarged inflammatory lymph nodes cannot be differentiated from metastatic nodes (Ferrucci et al., 1990). The use of ultrasmall superpara¬magnetic iron oxide (USPIO) such as Ferumoxtran-10 (Ferrotran®, formerly Sinerem® or Combidex®) as a contrast agent for MRI could improve this diagnosis.
At present, lymph node metastatic involvement is one of the most important parameters of the prognosis and one of the indicators in the choice of different treatments, i.e., surgery, chemotherapy or radiotherapy.
Ferrotran®-enhanced MRI can provide a non-invasive and non-irradiative imaging tool for accurate N-staging, even in case of normal-sized lymph nodes carrying micrometastases, in one single MR examination which would complete the evaluation of primary tumour spread in pelvic cancer patients.
For prostate cancer patients the determination of the extent of the tumour spread in the lymph nodes is an important information, which cannot be answered sufficiently with current imaging technology.
The clinical studies performed with Ferumoxtran-10 clearly showed that Ferumoxtran-10-enhanced MRI offers higher diagnostic performance than conventional MRI, and is sensitive and specific for the detection of lymph-node metastases (Wu et al., 2011). Also, the technique shows a better sensitivity than any other non-surgical technique available. Ferumoxtran-10 enhanced MRI also provides a very high negative predictive value for the lymph nodes present in the surgical area of lymphadenectomy as well as outside this area.
Thus Ferumoxtran-10-enhanced MRI is expected to improve prostate cancer N-staging and to provide high sensitivity and specificity which are not reached by the conventional MRI (sole measurement of node size of the lymphatic chains draining the prostate gland).
This pivotal study is designed to achieve marketing authorisation for

Ferumoxtran-10, taking into account the flaws in design and evaluation of MRI scans of the former phase 3 study (ALS 44-003-A) which was withdrawn from marketing application by Guerbet in 2007. The previous study failed to demonstrate a consistent and statistically significant benefit in sensitivity and failed to confirm non-inferiority with regard to specificity due to inconsistent results between readers of the MRI scans.
Saving Patients* Lives Medical B.V. has decided to attempt a new marketing authorisation application based on a new and better-designed phase 3 study, using up-to-date equipment.
Taking into account previous recommendations of the EMEA scientific advice as well as the recent BfArM scientific advice on 12-Apr-2018, Saving Patients* Lives Medical B.V. has carefully designed the planned pivotal Phase III study SPL-01-001 and believes that with this new fully blinded centralised reading of the MR images, the study can prove the diagnostic performance of Ferumoxtran-10, within the context of a new MA submission.

Study objective

Primary Objectives
1. To confirm superiority of Ferrotran®-enhanced MRI over unenhanced MRI in sensitivity to detect metastases in normal size pelvic lymph nodes in using histopathology after lymph node dissection as established reference method (Gold Standard).
2. To confirm non-inferiority of Ferrotran®-enhanced MRI compared with unenhanced MRI in specificity with a margin of 15% in using histopathology after lymph node dissection as established reference method (Gold Standard).

Secondary Objectives

1. To confirm non-inferiority of Ferrotran®-enhanced MRI compared with unenhanced MRI in sensitivity with a margin of 15% to detect any pelvic lymph node metastases in using histopathology after lymph node dissection as established reference method (Gold Standard).
2. To evaluate the number and sites (gross- and sub-regions) of affected lymph nodes removed and not removed by ePLND comparing the unenhanced MRI at follow-up and the pre-surgery MRIs (unenhanced and Ferrotran®-enhanced).
3. To assess the clinical safety and tolerability of a single slow drip Ferrotran® infusion.
4. To assess the impact of Ferrotran®-enhanced MRI on the patient management plan.

Study design

It will be a confirmatory, prospective, open-lable, single-arm, reader-blinded, multi-centre phase 3 study. For an individual patient, the total duration of the study, including screening period, will be 9 to 18 weeks. the study as a

whole will take about 1.5 tot 2 years, depending on the recruitment.

Screening
Informed consent is to be obtained before any screening-related assessments will be conducted.
Patients will be screened for eligibility for the study from Day -28 and up to one day (Day -1) before treatment with Ferrotran®. Eligibility criteria include the availability of histologically confirmed diagnosis, tumour staging and PSA assessment as part of the standard of care.
After signing the informed consent form, patients will undergo the following screening investigations and procedures:
• Review of inclusion/exclusion criteria (incl. information on histologically confirmed diagnosis, tumour staging and PSA level as taken from standard of care investigations, completed Briganti nomogram)
• Demographics & medical history (incl. concurrent conditions and concomitant medication)
• Physical examination
• Vital signs
• 12-lead ECG
• Safety laboratory (haematology, biochemistry and urinalysis)
• Concomitant medication (up to 4 weeks prior to Day 0)
• Baseline findings
• Unenhanced/native MRI of the pelvic lymph nodes will serve as Baseline MRI scan, unless available from previous work-up (in any case, not conducted any longer than 28 days before treatment and in compliance with parameters set out in the imaging manual).
• Definition of a clinical patient management or treatment plan by completion of a pre-defined questionnaire based on all available clinical information (except Ferrotran®-enhanced MRI).

Treatment (Day 0)
On Day 0, the eligibility will be confirmed as per the screening results.

Pre-dose:
Assessments performed on Day 0 at pre-dose will include:
• Physical examination
• Vital signs
• Concomitant medication
• Baseline findings
• Weight for the calculation of Ferrotran® dose
Baseline results are findings from physical examination and vital signs recorded on Day 0 pre-dose. Baseline results for 12-lead ECG and safety laboratory parameters will be taken from screening investigations.

Administration of Study Drug (Time-point 0):
A weight-adjusted dose of Ferrotran® will be slowly infused IV over approximately 30 minutes at an infusion rate of max. 4 mL/min.

The solution must be administered within 24 hours after dilution.
Patients must be closely monitored by study personnel for 60 minutes from the start of the infusion for any allergic or infusion-related reactions as well as other AEs.
In case of any AE the infusion must be stopped immediately and appropriate action must be taken. If there are only mild AEs (e.g. back pain, flush) the infusion can be continued at a lower rate after resolution of the symptoms.

Time-point 4 Hours (±15 Minutes) after End of Infusion:
At 4 hours (*15 minutes) after the end of the Ferrotran® infusion, but before discharge, the following will be assessed:
• Vital signs
• Safety laboratory (haematology, biochemistry and urinalysis)
• 12-lead ECG
• Concomitant medication
• Adverse events

Imaging on Day 1 (24 to 36 Hours after End of Infusion):
• Ferrotran®-enhanced pelvic MRI (searching sequence only, no characterisation of lymph nodes)
• Adverse events
• Concomitant medication

Safety Follow-up (Day 7 and/or One Day before or on Day of Surgery)
The safety follow-up assessments will be performed on Day 7 for all patients. For patients with a scheduled surgery after Day 7 until Day 42, the following assessments will be repeated either one day before or directly on the day of surgery:
• Physical examination
• Vital signs
• 12-lead ECG
• Safety laboratory (haematology, biochemistry and urinalysis)
• Concomitant medication
• Adverse events
In the time period after the Ferrotran®-enhanced MRI evaluation by local readers, but before RP/ePLND, the clinical management or treatment plan will be revised by completing a pre-defined questionnaire based on all available clinical information including Ferrotran®-enhanced MRI.

Surgery (Day 7 to Day 42)
Before surgery, MRI scans will be read by local readers who are trained to harmonise their reading performance in a standardised manner. Results from the reads of the local readers have to be available before surgery and will be communicated in time to the urology surgeons so that they can schedule the surgery thereafter. Results from MRI scans in multiple views (axial, sagittal, coronal), including a MR-angiography sequence will serve as a diagnostic tool to guide the lymph node dissection.

All medications and therapies that were given as part of routine procedure for the surgery will be reported within the frame of this clinical study in cumulative rather than individual doses per generic drug.
The dissected tissue containing the lymph nodes will be collected per defined region in at least 8 vials with a fixating agent. After fixation, the tissue will be transferred to the histopathologist.
The blinded off-site reading will be done independently of surgery.
The pre-scheduled radical prostatectomy with the ePLND will be performed as per standard of care.

EoS Visit (8±1 weeks after Surgery)
At 8 (±1) weeks after the prostatectomy with ePLND, a PSA measurement and a native, unenhanced MRI of the pelvic region will be performed for evaluation of secondary efficacy endpoints, i.e. identification of metastatic lymph nodes that have been overlooked and thus were not removed during the ePLND.
In addition, blood and urine samples will be collected to assess long-term safety of Ferrotran®.
Any treatment (radiation, chemo-, immuno- or hormonal therapy) which might be scheduled as standard of care after the surgery shall be omitted until the FUP MRI was performed. Thus, if the investigator deems such excluded treatment necessary, s/he should aim to commence the treatment AFTER the unenhanced FUP MR imaging. In these special cases, the unenhanced FUP MRI and the long-term safety lab can be brought forward (if necessary) and will not have to be scheduled 8 (±1) weeks after the surgery.
Any AEs that will be recorded during the FUP-MRI are considered (MRI or blood sampling)-procedure-related, unless an abnormal safety lab value constitutes an AE.
The purpose of the FUP MRI is to reveal any lymph nodes that have possibly been overlooked during surgery.

Intervention

Not applicable

Study burden and risks

Benefit-Risk-Assessment
More than 1660 patients or healthy volunteers have received Ferumoxtran-10 in clinical studies. The safety profile of Ferumoxtran-10 is well known and the product can be considered safe with a good tolerability. The safety data pooled over all 37 clinical studies that were conducted with Ferumoxtran-10 so far, confirm that whatever the rates compared (number of AEs, or patients with at least one AE), tolerance in the Ferumoxtran-10 group was similar to that of the placebo group. 386 (23.2%) of the 1663 study participants who received Ferumoxtran-10 reported at least one AE, versus 19 (25.3%) of the 75 patients who received placebo.

The indication for Ferumoxtran-10-enhanced MRI in the diagnosis of lymph node metastases in MRI, is justified in view of the major therapeutic consequences associated with better staging of prostate cancer patients, because this technique provides a non-invasive and non-irradiative imaging tool which helps in the N staging of prostate cancer patients, and which performs better than current imaging modalities in prostate cancer.
Indeed, in the case of pelvic cancers, such as prostate, bladder and uterus cancers, surgery is currently considered the only method capable of excluding metastatic spread to the lymph nodes that is not without complications, or even mortality.
Thus, Ferumoxtran-10-enhanced MRI would help to decrease the number of patients unnecessarily undergoing a radical surgery (prostatectomy) and would provide a non-invasive and non-irradiative imaging tool to enhance detection of malignant lymph nodes (the technique shows a better sensitivity than any other non-surgical technique available). Ferumoxtran-10-enhanced MRI also provides a very high negative predictive value for the lymph node present in the surgical area of lymphadenectomy as well as outside this area.
This would allow the patient to benefit for the best treatment according to his/her status, and to avoid an invasive surgery and a long surgical procedure.
Furthermore, it is fair to say that Ferumoxtran-10-enhanced MR generates many fewer false negative patients than other imaging modalities with respect to lymph node metastases detection, and as many or more false positive patients, and that both the false negatives and the false positives produced by this technique will decrease in the future in parallel with advances in MR technology. Such advances are currently under way with optimization of the sequences that improves spatial resolution in the pelvic wall area as well as in the para-aortic and para-metrial tissues for instance; also with high field MRI (3T). It should also benefit from the expertise that needs to be acquired (detection of lymph nodes and recognition of these structures as such, and signal assessment on Ferumoxtran-10-enhanced images to differentiate benign from malignant nodes). This may be done by providing radiologists with appropriate training in terms of MR sequence parameters and planes, lymph node anatomy, appearance of benign and malignant lymph node using Ferumoxtran-10-enhanced images. An appropriate educative tool could be a learning set of images illustrating the most representative cases.
According to Barentsz et al. [Barentsz, 2005; Barentsz et al., 2007] Ferumoxtran-10 has an important clinical impact, as the diagnosis will be more precise and less invasive to obtain. Subsequently, this will reduce morbidity and health care costs.

General Safety
From the ample safety data on Ferrotran® gained so far from more than 1660 study subjects (healthy volunteer or patient), it can be concluded that the AEs most frequently occur within a short period of time after the infusion.
Most hypersensitivity reactions, especially after first administration of Ferrotran®, occurred immediately or within an hour after administration, although the possibility of delayed reactions up to several days after the

infusion cannot be completely ruled out.
The most frequently reported AE after Ferrotran® infusion was back pain. In 50% of the events, back pain began within the first 5 minutes after administration and resolved before the end of the infusion. The occurrence of back pain can be reduced by infusing Ferrotran® at higher dilutions and lower infusion rates.
The great majority of the first observed symptoms consisted of hypersensitivity reactions (merging pruritus, urticaria, rash and erythema), resembling type I allergic reactions as regards their clinical characteristics. These symptoms usually occurred very rapidly, during infusion, and led to temporary or definitive discontinuation of the infusion in a number of cases. Other symptoms (*flushing* and *feeling hot*), when reported with no associated allergic-like events, could correspond to reactions such as those classified as *infusion-related reactions*, not being specifically linked to an underlying allergic physio-pathological mechanism.
The incidence of *chest pain* was very similar between the Ferrotran® group (1.4%) and the placebo group (1.3%), and the available data do not provide sufficient information for discussing their physiopathology.
The incidence of *hypotension* or *blood pressure decrease* was very low: 12 AEs (0.7%), of which 3 were reported to be serious and considered to be related to Ferrotran®.
Medical supervision for 60 minutes from the start of the infusion is required particularly because of the potential for severe allergic or infusion-like reactions. Resuscitation material (oxygen equipment, adrenaline, antihistamines and corticosteroids) must be available during administration of the product to treat such reactions. Most of these reactions occur immediately or within an hour after the start of the infusion and cannot be predicted. Their mechanism is not dose-dependent. If such reactions occur, the infusion must be stopped immediately and appropriate treatment must be administered.
A risk of hypersensitivity reactions may exist even when Ferrotran® is administered for the first time. Most hypersensitivity reactions occur immediately or within an hour after Ferrotran® infusion. However, the possibility of delayed reactions, occurring up to several days after the infusion, cannot be excluded. Hypersensitivity reactions can be more severe in patients treated with beta-blockers, particularly in patients with bronchial asthma. These patients may be refractory to standard treatment of hypersensitivity reactions with beta-agonists. Patients with a history of hypersensitivity, including allergy to an iodinated contrast agent, should be carefully monitored, as the risk of adverse reactions, particularly allergic reactions, is increased in these patients.
In case of back pain, the infusion must be stopped and the patient must be kept under medical surveillance until the symptoms resolve. The administration of Ferrotran® can then be continued under medical supervision by reducing the infusion rate.
In case of extravasation, the severity of the lesions should be assessed and adapted treatment implemented.
Another aspect that should be considered is that between Day 7 and Day 42 of the planned study, the pre-planned radical prostatectomy with ePLND will be

performed. It cannot be ruled out that this major surgery is associated with several AEs. This might lead to a bias with regard to further results of safety assessments and AE monitoring performed after the surgery and render any assessment of relationship of the AE to the Ferrotran® infusion not verifiable.
During a surgery like RP with ePLND considered here for the prostate cancer patients, the blood loss or transfusion amounts are in the range of 0.5 L to >1 L; i.e. approx. 10% to >20% of the entire blood volume of 4-6 L, will be exchanged. The iron content in blood is around 1 g/L and hence 0.5 to >1 g will be lost/exchanged during a surgery. This is about 3-5-fold the total amount of Ferrotran® administered.
Since the bleeding will cause major changes in the entire iron metabolism and also all iron related blood parameters, it seems impossible to measure the impact of Ferrotran® infusion on iron and other parameters in the blood during and after the surgery. Additionally, all other parameters such as the inflammation markers will of course also change considerably after the surgery.

Iron Overload
It is well known that the magnetic resonance signal in the lymph nodes returns to baseline about 7 days after Ferrotran® infusion because the iron contained in Ferrotran® is incorporated into the body*s iron store and is progressively found in the red blood cells (haemoglobin). Like endogenous iron, it is eliminated very slowly since only 16% to 21% of the iron injected is eliminated after 84 days via the faeces (urinary excretion negligible < 1%). It is noteworthy that a single dose of Ferrotran® contains less iron than a single unit (200 mL) of whole blood.
The plasma elimination half-life in humans is 21 to 30 hours (mean: 26.6 hours) in humans and is not dose-dependent. The volume of distribution is between 2.6 and 3.71 (mean: 2.8 L), which is equivalent to the plasma compartment. The total clearance is between 0.018 and 0.027 L/day/kg (mean: 0.0022 L/day/kg).
Moreover, the magnetic resonance signal in Ferrotran®-enhanced MRI scans returns to baseline about 7 days (lymph nodes) and 1-2 months (liver) after the administration of Ferrotran®, indicating the uptake of the iron nanoparticles into the mononuclear phagocytic system and their progressive biodegradation (loss of magnetic properties of the nanoparticles) and incorporation into the whole body iron system.
Intravenous iron has been used for more than 10 years to treat iron deficiency anaemia in patients unable to absorb oral iron preparations. The preparation Ferinject 50 mg (iron carboxymaltose) is also an iron-sugar complex, and received EU marketing authorisation in 2007. According to the SmPC, patients with iron deficiency anaemia usually receive intravenous doses of up to 1000 mg iron per week over longer periods of time.
As iron is expected to be incorporated into the metabolism, and is an essential trace element, the iron itself at physiological doses is not linked to any safety concerns, but the intravenous administration was shown to be accompanied by immediate hypersensitivity reactions in some cases.
Therefore, the EMA Committee for Medicinal Products for Human Use (CHMP) issued a review of intravenous iron-containing medicines used to treat iron deficiency

and anaemia in 2013, and concluded that the benefits of these medicines are greater than their risks, provided that adequate measures are taken to minimise the risk of allergic reactions (EMA recommendations EMA/579491/2013).
Oral iron preparations such as ferro sanol® duodenal are given in doses of 100 mg per day for the prevention and treatment of iron deficiency, and are available over-the counter. These preparations are taken daily over months or years, without any safety concerns. Intravenous iron is given at doses of 1000 mg per week over long periods of time without any safety concerns except the immediate risk of hypersensitivity reactions.
None of the total 1663 study subjects who have received Ferrotran® infusion experienced any AEs or other safety problems related to the iron load after Ferrotran® infusion. Patients with disorders associated with iron overload or disturbances in the utilisation of iron (e.g., haemochromatosis, haemosiderosis, chronic haemolytic anaemia with frequent blood transfusions) will be excluded from participation in the study.
Despite the fact, that during surgery the patient might suffer a significant blood loss, SPL has decided to assess long-term safety at 8 weeks after surgery taking further blood and urine samples.

Conclusions
The dose of 203 mg Fe for a 78 kg person in a single infusion of Ferrotran® is about twice the long-term daily dose of OTC oral iron supplements, about one fifth of the regular 1000 mg weekly infusions of intravenous iron for the treatment of iron deficiency anaemia, and between 0.0058% and 0.0041% of the total body iron. The amount of iron administered within the study is even below or in the range of normal iron uptake by food.
Therefore, this dose is considered to be well within the range of physiological iron supplementation, and a safety follow-up of one week is considered to be more than adequate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Voluntarily given and written informed consent.
2) Male >=18 years of age.
3) Histologically newly-confirmed adenocarcinoma of the prostate.
4) Medium to high risk for lymph node metastasis, defined by either:
a) PSA >= 10 ng/ml or
b) Gleason-Score >= 7 or
c) Stage cT2b or cT2c or T3 or T4
5) Patients scheduled for radical prostatectomy (RP) with extended lymph node dissection (ePLND) between Day 7 and Day 42 after Ferrotran®-enhanced MRI.
6) Consent to practice contraception until end of study, including female partners of childbearing potential. Effective contraceptive measures include hormonal oral, injected or implanted female contraceptives, male condom, vaginal diaphragm, cervical cap, intrauterine device.
7) Preoperative PSA, clinical T-stage, primary Gleason grade, secondary Gleason grade.

Exclusion criteria

1) Any contraindication to MRI, as per standard criteria.
2) Any radiation therapy or systemic antiproliferative (chemo-, immuno, or hormonal) therapy for prostate cancer (Lupron, Taxotere, Casodex, Eulexin, Zoladex, etc.) prior to screening and until after post-surgery FUP MRI.
3) Known hypersensitivity to Ferrotran®or its components such as dextran.
4) Known hypersensitivity to other parenteral iron products.
5) Acute allergy including drug allergies and allergic asthma.
6) Evidence of iron overload or disturbances in the utilisation of iron (e.g., haemochromatosis, haemosiderosis, chronic haemolytic anaemia with frequent

blood transfusions).
7) Presence of liver dysfunction.
8) Any other investigational medicinal product within 30 days prior to receiving study medication until end of study visit.
9) Simultaneous participation in any other clinical trial.
10) Abnormal safety laboratory values at screening or baseline that are assessed by the principal investigator as clinically relevant.
11) Patients not able to declare meaningful informed consent on their own (e.g. with legal guardian for mental disorders), or other vulnerable patients (e.g. under arrest).

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2021
Enrollment:	36
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ferrotran
Generic name:	Ferumoxtran-10

Ethics review

Approved WMO

Date:	14-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-07-2022
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Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-10-2022
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Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
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Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-004310-18-NL
CCMO	NL70361.091.20