EFFECT OF FERRIC CARBOXYMALTOSE ON EXERCISE CAPACITY AFTER KIDNEY TRANSPLANTATION: A MULTICENTER RANDOMIZED CONTROLLED TRIAL

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To study the effects of FCM on exercise tolerance, haematinic parameters, quality of life, cardiac function, muscle function, bone and mineral parameters, microbiota, the immune system, the incidence of infections, allograft failure and mortality in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON52637

Source
ToetsingOnline

Brief title
EFFECT KTx

Condition

- Heart failures
- Iron and trace metal metabolism disorders
- Renal disorders (excl nephropathies)

Synonym
Iron deficiency after renal Transplantation; Iron shortage after kidney transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nierstichting,Vifor Fresenius Medical Care Renal Pharma

Intervention

Keyword: Cardiac Output, Iron deficiency, Renal transplantation, Six minute walk test

Outcome measures

Primary outcome

The main study parameter is change in six-minute-walking test score.

Secondary outcome

Secondary parameters are haematinic parameters, quality of life, cardiac function, muscle function, bone and mineral parameters, microbiota, the immune system, the incidence of infections, allograft failure and mortality in iron-deficient kidney transplant recipients (KTRs).

In a subgroup of participants the antibody and lymphocyte response after vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) will also be assessed as a secundary endpoint.

We will also assess the in vitro effect of iron deficiency induced by deferoxamine on lymphocyte proliferation, differentiation and cytokine and IgG production.

Study description

Background summary

Iron deficiency is a common phenomenon in kidney transplant recipients and is associated with unfavourable prognosis and impaired exercise tolerance. We

hypothesize a beneficiary effect of Ferric Carboxymaltose (FCM) on exercise tolerance and quality of life.

Study objective

To study the effects of FCM on exercise tolerance, haematinic parameters, quality of life, cardiac function, muscle function, bone and mineral parameters, microbiota, the immune system, the incidence of infections, allograft failure and mortality in iron-deficient kidney transplant recipients (KTR*s).

Also, the in vitro effect of iron deficiency on lymphocyte growth and function wil be studied to support possible results of the intervention study.

Study design

We will perform a Randomised Controlled Clinical Trial to compare Ferric Carboxymaltose with a placebo.

We will also perform a pilot in vitro study using blood from healthy subjects. Blood products will be treated with iron chelating agent deferoxamine after blood withdrawal.

Intervention

The intervention group will receive 500mg of FCM every six weeks, with a total of four dosages. The other group receives an intravenous placebo solution. No intervention will be performed in healthy volunteers.

Study burden and risks

Treatment of iron-deficient KTR*s with FCM contains some risks. Mild adverse effects may occur and severe reactions, which are extremely rare, cannot be excluded. The long term effects of FCM-induced hypophosphatemia on the bone density are unknown. FCM has been thoroughly studied and is frequently used in various populations. It has proved to be a safe and highly effective medicine to treat iron deficiency.

Burden and risks for helathy volunteers are minimal. A blood collection may cause mild pain.

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. Kidney transplant recipients
2. Iron deficiency, defined by a ferritin level of <=100 ug/L, or 100-299 ug/L combined with a transferrin saturation of <=20%
3. At least four months after transplantation at the time of inclusion (or: six months after transplantation at baseline)
4. Age more than 18 years
5. Ability to comply with the study protocol
6. Informed consent

Exclusion criteria

1. Intolerance of any intravenous iron solution
2. Severe (Hb <10.4 g/dL, <6.5 mmol/L), microcytic or progressive anemia
3. A positive feces occult blood test or known source of gastrointestinal blood loss after endoscopy

4. Blood transfusion in the past six weeks
5. Polycythemia (Hb >15.3 g/dL, 9.5 mmol/L)
6. Haemochromatosis
7. An estimated glomerular filtration rate (eGFR) of <= 30 ml/min per 1.73 m2 at screening
8. Resting heart rate of more than 120 per minute
9. Unstable angina or myocardial infarction during the previous month
10. Disability to walk
11. Hypophosphatemia (serum phosphate <0.35 mmol/L)
12. Pregnancy
13. Severe hyponatremia (Na <130 mmol/L) or fluid retention
14. Participation in another interventional trial

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-10-2019
Enrollment:	158
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Comirnaty
Product type:	Medicine
Brand name:	COVID-19 vaccine Moderna

Product type:	Medicine
Brand name:	Ferinject
Generic name:	Ferric Carboxymaltose
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-09-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-07-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-11-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-06-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-01-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2018-002571-18-NL
ClinicalTrials.gov	NCT03769441
CCMO	NL67065.042.18