Effect of Iron deficiency on skeletetal muscle metabolisme in HFpEF

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Objective: To assess if skeletal muscle metabolism is impaired in HFpEF patients with iron deficiency compared to HFpEF patients without iron deficiency?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON55673

Source
ToetsingOnline

Brief title
Iron Muscles

Condition

- Heart failures

Synonym
diastolic heart failure, iron deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: bedrijven

Intervention

Keyword: heart failure, HFpEF, iron deficiency, muscle metabolisme

Outcome measures

Primary outcome

The main study parameters is PCr/ATP ratio, a measurement of phosphocreatine to

ATP ratio using MR spectroscopy. This assess skeletal muscle metabolism.

Secondary outcome

Secondary parameters/endpoints are:

- Microvascular function (glycocalyx thickness, % skin hyperaemic response)

- Exercise tolerance (6 minute walk test distance)

Study description

Background summary

Diabetes, obesity and hypertension, all highly present comorbidities in HFpEF, seem to drive this disease by inducing low-grade systemic inflammation which in turn induces microvascular dysfunction and activates a cascade of events.
Several studies have demonstrated that HFpEF is a systemic disease that affects not only cardiac, but also peripheral muscle energy metabolism. Iron deficiency (ID) could be an important contributor in this pathophysiological process.
Iron deficiency is present in 50% of chronic HF patients. Although HFpEF was not excluded from these cohort studies, it mainly included HF with reduced ejection fraction (HFrEF).
We hypothesize that ID is an important factor in the limitation of exercise capacity in HFpEF. Systemic low-grade inflammation does not only lead to microvascular dysfunction but also to iron deficiency. Iron deficiency has a direct effect on the muscle. Not only on the cardiac muscle but also the skeletal muscle is affected, impairing muscle contraction strength but also energy metabolism. The primary focus of this study will be delivering proof that the alterations in the muscle are more severe in HFpEF patients with ID compared to without ID.

Study objective

Objective:
To assess if skeletal muscle metabolism is impaired in HFpEF patients with iron deficiency compared to HFpEF patients without iron deficiency?

Study design

Prospective case-control study

Study burden and risks

There is a minimal burden associated with participation in this study. Measurements of ID are performed as part of routine examinations in the outpatient clinic.

1. MR spectroscopy is a non-invasive, non-radiation imaging technique. CMR has a low risk of contrast reaction. To date, MRI investigations have been performed in over 200 million patients. Worldwide and are regarded as extremely safe. MRI is painless and has no known short-term or long-term biological adverse effects. Deaths have only been reported when proper safety precautions were not taken.
Risks: There are very few risks known to be associated with MRI:
Changing radiofrequency pulses may produce heat. This is not known to cause any side effects. Loose metal objects in the patient or in the scanner room may cause damage to
the patient. When appropriate precautions are taken, this is rare to occur.

2.Glycocalyx thickness measurement is a non-invasive, endothelial function measurement method. This method has no contra-indications or adverse effects.

3.Heat-induced skin hyperaemic response, is a non-invasive, endothelial function measurement method. This method has no contraindications or adverse effects. The warm electrodes (warmth until 44° C) are not painful and just a slight local warmth can be felt.

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

All patients: presence of heart failure with preserved ejection fraction (HFpEF) according to ESC guidelines: (1) signs and/or symptoms of heart failure (2) LVEF >= 50%, (3) elevated levels of natriuretic peptide, (4) relevant structural heart disease (LVmass index >95 in women, >115 in men; or LA enlargement, LAVI >34 ml/m2), or diastolic dysfunction (E/e' >= 13, or e'<9). Patients with Iron deficiency: serum ferritin < 100 µg/L or serum ferritin between 100-299 µg/L in combination with a transferrin saturation < 20%.

Exclusion criteria

- any iron supplement during last 6 months prior to inclusion
- any chemotherapy in last year
- significant peripheral artery disease
- contra indication for CMR, such as metallic implant, pacemaker/ICD or claustrophobia, body weight >130kg.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2019
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20027
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65600.068.18
OMON	NL-OMON20027