Oxidative skeletal muscle metabolism in chronic heart failure patients with and without iron deficiency

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To quantify the effect of ID on skeletal oxidative metabolism in patients with chronic HF with either preserved (HFpEF) or reduced (HFrEF) left ventricular ejection fraction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON52482

Source
ToetsingOnline

Brief title
Oxidative exercise capacity in chronic HF with and without ID

Condition

- Heart failures
- Iron and trace metal metabolism disorders

Synonym
heart failure, iron deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Heart failure, Iron deficiency, Oxidative exercise capacity

Outcome measures

Primary outcome

Bulk change of quadriceps phosphocreatine and inorganic phosphate content

during exercise, pH time course during exercise and kinetics of oxidative ATP

and phosphocreatine (PCr) resynthesis post-exercise.

Secondary outcome

Not applicable.

Study description

Background summary

Iron deficiency (ID) is comorbidity in heart failure (HF) patients with high prevalence and severe clinical consequences. Multiple studies have shown that ID in HF patients impairs exercise capacity, quality of life and outcome. It is currently unknown whether these detrimental consequences of ID are due to cardiovascular or hematologic effects, or deteriorated peripheral muscle metabolism and function.

Study objective

To quantify the effect of ID on skeletal oxidative metabolism in patients with chronic HF with either preserved (HFpEF) or reduced (HFrEF) left ventricular ejection fraction.

Study design

Observational study using in vivo noninvasive 31P magnetic resonance spectroscopy to determine oxidative skeletal muscle metabolism at rest and during incremental exercise.

Study burden and risks

Participating subjects visit the UMCG only once for approximately one and a half hour. Eligible subjects will be screened for contra-indications for either MRI testing and/or (maximal) exercise testing. Subjects with contra-indications for (maximal) exercise MRI testing will not be enrolled in the study. Subjects do not have direct benefits from participating in this study. Previously conducted 31P MRS studies in adult subjects with muscular diseases, cystic fibrosis and chronic heart failure showed no adverse and/or serious adverse events.

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

For HFrEF patients:
- Diagnosis of chronic HF of either ischemic or non-ischemic etiology;

- Stable, evidence-based medical therapy for HF;
- LVEF <40% measured <5 year prior to inclusion;
- NYHA class II - III (symptomatic HF) at moment of inclusion;

For HFpEF patients:
- Diagnosis of chronic HF of either ischemic or non-ischemic etiology;
- LVEF >40% measured <5 year prior to inclusion;
- Left atrial volume index (LAVI) >34 mL/m2 or left ventricular mass index >=115 g/m2 (for males) or >=95 g/m2 (for females) or E/e* >=13 or mean e* (septal and lateral) <9 cm/s, as measured on echocardiography <1 year prior to inclusion;
- NYHA class II - III (symptomatic HF) at moment of inclusion;
- Serum NT-proBNP >=125 pg/mL when in sinus rhythm; >300 pg/mL when in atrial fibrillation.

Additional inclusion criterion for subjects with ID:
- Iron deficiency, defined as TSAT <20%.

For control subjects:
- No diagnosis of heart failure
- No diagnosis of severe vascular or (neuro-)muscular disease

Exclusion criteria

- Age <18 years
- Unable or unwilling to undergo exercise MRI (e.g. pregnancy, physical disabilities, claustrophobia)
- The presence of ferromagnetic material in/on the body which cannot be removed (e.g. non-MRI-compatible cardiac devices, tattoos containing ferrous ink)
- History of erythropoietin stimulating agent, intravenous iron therapy and/or blood transfusion <3 months prior to study enrolment
- Moderate anaemia, defined as Hb <7 mmol/L for both men and women
- Oral iron therapy >100 mg/day <4 weeks prior to study enrollment
- Unable to understand study procedures
- Unable or unwilling to provide informed consent

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2022
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
CCMO	NL64308.042.18