# Prevalence in Iron deficiency Acute Heart Faliure

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON28189

**Source**
NTR

**Brief title**
Prevalence HF

**Health condition**

heart failure, iron deficiency

### Sponsors and support

**Primary sponsor:** Maastricht University Medical Centre ( MUMC)
Prof Dr Brunner
**Source(s) of monetary or material Support:** VIFOR

### Intervention

### Outcome measures

**Primary outcome**

This study aims to analyse the prevalence of iron deficiency (ID) in patients with an episode of acute heart failure at different time points (t0 = within 24(+12h) hours of admission due to acute decompensated heart failure, t1 = after stabilisation and within 0-2 days prior to discharge, t2 = 6 weeks after discharge (+- 2 weeks, but never earlier than 4 weeks after

discharge).

Iron deficiency is defined as serum ferritin <100µg/l or serum ferritin =100-299µg/l and transferrin saturation <20%.

**Secondary outcome**

To determine at what time point screening for ID is reliable after a patient is hospitalized due to an acute episode (guidance for cardiologists).

To analyse the prevalence of ID in subgroups (female, LVEF, NYHA, co-morbidities (hypertension, diabetes mellitus, COPD/asthma, CVA/TIA, cancer, anaemia, systemic inflammatory disorders, valve disease, atrial fibrillation), eGFR and CRP and anemia).

For possible later analyses, left-over of already drawn serum may be stored (at discretion of the investigators, until further notice in MUMC Maastricht, Zuyderland Hospital Heerlen and Amphia hospital Breda only). Such analyses might include measurement of hepcidine or soluble transferrin-receptor, among other biomarkers, to better define the role of iron deficiency in the acute setting of HF. This may also give insight if measurements of ferritin provide reliable results or if definition of ID should be different in the acute setting.

# Study description

**Background summary**

SUMMARY

Rationale:

The cause of iron deficiency (ID) could be gastrointestinal blood loss, poor nutrition, menstruation in fertile women, malabsorption or (chronic) inflammation, as often present in chronic disorders. Several studies showed that treatment of ID may reduce heart failure (HF)-hospitalisation, improve quality of life and alleviate heart failure (HF) symptoms of HF patients. The recently published ESC guidelines 2016 for acute and chronic heart failure recommend to consider to treat ID.

An overall prevalence of 50% has been shown in a partially Dutch cohort study in chronic HF patients. In patients with acute HF, ID may be also very common, with a prevalence of 65%.

However, both prevalence percentages were not measured in real-life cohorts. Thus, it is not yet clear if there is a higher prevalence during an acute episode of heart failure as compared to chronic HF (65% vs 50%). In fact, it may be even underestimated as serum ferritin levels rise during acute inflammation as it is classified as acute phase protein, what probably masks iron deficiency. Does this give false negatives at screening for ID? Which patients are identified with ID in acute setting and are those the same patients who are identified with ID later on? What is the prevalence of real-life cohort? What are reliable time-points to measure ID in HF patients?

The expectation is that after stabilization of the HF patients, the serum ferritin values are more reliable and lab tests will show ID in >30% of all admitted patients.

Objective:

To assess the prevalence of ID in patients with an episode of acute heart failure at different time points.

Study design:
Prospective, non-interventional study assessing the prevalence of ID in a real-life cohort.

Study population:

All patients (>18yr) admitted due to an episode of acute heart failure.

Main study parameters/endpoints:

The main study parameter is the percentage of patients with ID within the total group of patients with acute heart failure and the change of ID from admission (t0) to 6 weeks after discharge (t2) via blood sample by determining Hb, TSAT and Ferritine.

t0 = within 24(+12h) hours of admission due to acute decompensated heart failure; t1 = after stabilisation and within 0-2 days prior to discharge; t2 = 6 weeks after discharge.

**Study objective**

Asess prevalence of Iron Deficiency in patients with episode of acute heart Failure at different end points

**Study design**

t0: admission

T1: just before discharge

T2: 6 weeks after discharge

**Intervention**

none, observational study

# Contacts

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# Eligibility criteria

## Inclusion criteria

Age> 18 years

Admission with an episode of acute heart failure

### Exclusion criteria

- History of erythropoietin stimulating agent, IV iron therapy, and/or blood transfusion within 3 months prior to hospitalisation.

- Oral iron therapy at any doses in 4 weeks prior to hospitalization or iron containing multivitamins irrespectively of the dose of iron.

- History of receiving systemic chemotherapy and/or radiotherapy in 3 months prior to hospitalisation.

## Study design

### Design

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|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-02-2017 |
| Enrollment: | 1000 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Yes

## Ethics review

Positive opinion

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|---|---|
| Date: | 26-02-2018 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 50256
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL6868 |
| NTR-old | NTR7046 |
| CCMO | NL59894.096.16 |
| OMON | NL-OMON50256 |

# Study results