Prevalence in Iron deficiency Acute Heart Faliure

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28189

Bron
NTR

Verkorte titel
Prevalence HF

Aandoening

heart failure, iron deficiency

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (MUMC)
Prof Dr Brunner
Overige ondersteuning: VIFOR

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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%.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

t0: admission

T1: just before discharge

T2: 6 weeks after discharge

Onderzoeksproduct en/of interventie

none, observational study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age> 18 years

Admission with an episode of acute heart failure

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	26-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50256
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten