Prevalence of Iron Deficiency in acute heart Failure

Published: 09-03-2017
Last updated: 15-05-2024

The objective of this study is the collection of demographic data (like sex and age), medical data and treatment information during, and until 6 weeks after a hospital submission for heart failure.By doing this, a good insight will be gained for...

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

Summary

ID

NL-OMON50256

Source
ToetsingOnline

Brief title
Prevalence study

Condition

- Heart failures

Synonym
Failure of te heart function, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Farmaceutisch bedrijf,Vifor Pharma

Intervention

Keyword: Heart Failure, Hospitalisation, Iron Deficiency, Prevalence

Outcome measures

Primary outcome

Prevalence of iron deficiency according to the definition of the ESC guidelines

Secondary outcome

- Associations between type and measures of severity of heart failure and iron

deficiency;

- Time course of measures of iron (deficiency), heart failure and

co-morbidities

Study description

Background summary

In 2012 the European Society of Cardiology (ESC) published in her Guideline for acute and chronic heart failure a definition for iron deficiency.
The prevalence of iron deficiency according to this definition has not been sufficiently studied in a real life setting.

Study objective

The objective of this study is the collection of demographic data (like sex and age), medical data and treatment information during, and until 6 weeks after a hospital submission for heart failure.
By doing this, a good insight will be gained for this group of recently admitted hart failure patients, on the prevalence of iron deficiency in acute heart failure, based on data from blood samples taken.

Study design

An observational, epidemiological cohort study

Study burden and risks

At 3 moments in a period of approximately 16 weeks, blood samples will be analysed for assessing the iron deficiency. Bloodsample collecting will be done during an bloodsampling moment that is already necessary for regular treatment of patient
There is no extra burden or risk for the patient.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Westbroek 43
Breda 4822 ZX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Westbroek 43
Breda 4822 ZX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hospitalisation due to acute heart failure

Exclusion criteria

- History of erythropoietin stimulating agent, IV iron therapy, and/or blood transfusion in previous 3 months prior to hospitalisation.
- Oral iron therapy at any dose and/or continious use of iron containing multivitamines in previous 4 weeks prior to hospitalisation.
- History of receiving systemic chemotherapy and/or radiotherapy in previous 3 months prior to hospitalisation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-06-2017
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	04-09-2017
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	20-02-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	13-04-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	27-11-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-04-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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: 28189
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59894.096.16
OMON	NL-OMON28189