Pragmatic Urinary Sodium-based treatment algoritHm in Acute Heart Failure

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To assess the effect of natriuresis guided therapy in acute heart failure to improve diuretic response, decongestion, and clinical outcomes

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON55107

Source
ToetsingOnline

Brief title
PUSH AHF

Condition

- Heart failures

Synonym
Acute heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Heart Failure, Loop diuretics, Natriuresis

Outcome measures

Primary outcome

Co-primary outcome: total natriuresis after 24-hours first occurrence of heart

failure hospitalization or all-cause mortality after 6 months.

Secondary outcome

Secondary outcomes: 48- and 72-hour sodium excretion, length of hospital stay,

and percentage change in NT-proBNP at 48 and 72 hours

Safety endpoint: doubling of serum creatinine at 24- or 48-hours.

Study description

Background summary

Administration of loop diuretics to achieve decongestion is the current cornerstone of therapy for acute heart failure. Unfortunately, there is a lack of evidence of how to guide diuretic treatment. Recently, urinary sodium, as a response measure of diuretic response, has been proposed as a target for therapy.
The hypothesis of this study is that natriuresis guided therapy in patients with acute heart failure will improve diuretic response, decongestion, and reduce length of hospital stay, as well as heart failure rehospitalisations.

Study objective

To assess the effect of natriuresis guided therapy in acute heart failure to improve diuretic response, decongestion, and clinical outcomes

Study design

Randomised, controlled, open label study

Intervention

Natriuresis guided treatment versus standard of care

Study burden and risks

Since this is a pragmatic trial, the study will be embedded within the normal care of patients with acute heart failure, which already includes timed urinary collections and laboratory assessment at set time points. The patients in the natriuresis guided therapy will undergo additional urinary assessments, and undergo more stringent monitoring of response, and therefore might receive more intravenous diuretics. For study parameters, blood and urine will be collected at set time points. Survival and rehospitalisation will be assessed after 6 months by telephone call.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male of female >= 18 years of age
2. Primary diagnosis of acute/decompensated heart failure as assessed by treating physician
a. Acute heart failure de novo or exacerbation of known heart failure and diagnosis is based on criteria in the ESC HF guidelines
3. Requirement of intravenous diuretic use

Exclusion criteria

1. Dyspnoea primarily due to non-cardiac causes
2. Patients with severe renal failure impairment receiving dialysis or requiring ultrafiltration
3. Inability to follow instructions
4. Previous participation in this study
5. Any medical conditions that may put the patient at risk or influence study results in the investigator's opinion, or that the investigator deems unsuitable for the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	310
Type:	Anticipated

Ethics review

Approved WMO Date:	23-12-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-11-2021
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
ClinicalTrials.gov	NCT04606927
CCMO	NL75163.042.20