# Pragmatic Urinary Sodium-based treatment algorithm in Acute Heart Failure

Published: 23-12-2020 Last updated: 08-04-2024

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**

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#### Scientific

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## **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

NI

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