Targeted correction of plasma sodium levels in hospitalized patients with hyponatremia: a randomized, controlled, parallel-group trial with blinded outcome assessment

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

Summary

ID

NL-OMON54970

Source
ToetsingOnline

Brief title
HIT-trial

Condition

- Heart failures
- Hypothalamus and pituitary gland disorders
- Renal disorders (excl nephropathies)

Synonym
electrolyte disorder, salt-water disorder

Research involving

Human

Sponsors and support

Primary sponsor: Nefrologie
Source(s) of monetary or material Support: Erasmus Efficiency Grant;Swiss National Research Foundation

Intervention

Keyword: hyponatremia, mortality, rehospitalization, treatment

Outcome measures

Primary outcome

The primary outcome is the combined risk of death or rehospitalization within

30 days.

Secondary outcome

• Mortality within 30 days and 1 year

• Rehospitalization within 30 days and 1 year

• Time to death in days

• Time to first re-hospitalization in days

• Length of index hospital stay in days

• Number of falls within 30 days

• Number of fractures within 30 days and 1 year

• Sodium normalization rate at discharge of index hospitalisation

• Change of plasma sodium level from study inclusion until discharge of index

hospitalisation

• Change of plasma sodium level during the hospitalization

• Maximum sodium correction during index hospitalisation

• Time in days until first sodium normalization during index hospitalisation

• Time in days spent in normonatremia during index hospitalisation

Study description

Background summary

Hyponatremia is the most common electrolyte disorder with a prevalence of up to 30% in hospitalized patients. While treatment of acute hyponatremia with severe clinical symptoms due to cerebral edema is undisputed and straightforward, hyponatremia in general is usually considered asymptomatic or not clinically relevant. Accordingly, a recent observational study showed that appropriate laboratory tests to evaluate the etiology of hyponatremia were obtained in less than 50% of patients, leading to 75% of patients being still hyponatremic at discharge.
This is problematic in the context of increasing evidence, revealing an association of chronic hyponatremia with adverse effects such as gait alterations and falls, attention deficits, bone loss and fractures as well as disease-associated morbidity leading to increased rates of readmissions and mortality. Yet, there is a complete lack of randomized clinical trials with the primary aim to investigate whether correction of plasma sodium concentration counteracts the elevated risk of rehospitalization and mortality.

Study objective

The aim of this trial is therefore to determine the effects on mortality and rehospitalization rate of a targeted correction of plasma sodium concentration in addition to current standard care in hospitalized hyponatremic patients.

Study design

Pragmatic randomized (1:1 ratio) controlled, superiority, parallel-group international multi-center study with blinded outcome assessment.

Intervention

Targeted correction of plasma sodium concentration in addition to current standard care during index hospitalisation

Study burden and risks

Basic treatment of hyponatremia involves fluid restriction, saline infusions, diuretics or administration of oral urea. Those treatments have been known for years and are generally well tolerated, thus we estimate the risk of this study

intervention as minor.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All adult hospitalised patients with hypotonic hyponatremia <130mmol/l

Exclusion criteria

• Severe symptomatic hyponatremia in need of intensive care treatment and / or of acute correction with 3% saline
• Non-hypotonic hyponatremia with plasma osmolality >300 mOsm

• End of life care (palliative treatment)
• End stage kidney disease (dialysis)
• Acute liver failure
• Wernicke encephalopathy
• Hepatic encephalopathy during last 2 months
• Hepatorenal syndrome
• Patients in the isolation ward due to haematological diseases
• Pregnancy / breastfeeding
• Patients hospitalized for a predetermined fixed duration of 3 days or less (e.g. inpatient chemotherapy treatment)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2020
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	11-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	14-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL70054.078.19