

Fluid REStriction in Heart failure versus liberal fluid UPtake: the FRESH-UP study

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To investigate the effect of fluid restriction versus liberal fluid intake on QoL in chronic HF.

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

Summary

ID

NL-OMON52269

Source

ToetsingOnline

Brief title

FRESH-UP

Condition

- Heart failures

Synonym

Heart failure; chronic heart failure

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Chronic heart failure, Fluid restriction, Quality of life

Outcome measures

Primary outcome

Primary study parameters are QoL at 3 months after randomization, as assessed with the Kansas City Cardiomyopathy Questionnaire (KCCQ) Overall Summary Score.

Secondary outcome

Secondary and other study parameters are thirst distress using a validated thirst distress scale, QoL as assessed with the KCCQ Clinical Summary Score and each of the separate domains, QoL as assessed with a visual analogue scale (EQ-5D-5L), serum biomarkers (NT-proBNP, sodium, osmolality); and the occurrence of adverse events such as death, hospitalisations and need for iv-loop diuretics during the 6-month follow-up.

Study description

Background summary

Chronic heart failure (HF) is an increasing global health concern with over 20 million patients worldwide. Although it is common practice for clinicians to advice fluid restriction to prevent symptoms and hospitalisations due to fluid retention, there is no evidence to support this treatment strategy, as also stated in the most recent HF guidelines. Moreover, fluid restriction is associated with thirst distress and may adversely impact quality of life (QoL).

Study objective

To investigate the effect of fluid restriction versus liberal fluid intake on QoL in chronic HF.

Study design

Multi-centre open-label 1:1 randomized clinical trial with 6 months follow-up.

Intervention

On a background of standard guideline-directed medical therapy patients will be randomized to an advice by the treating physician and/or HF specialized nurse of either fluid restriction of 1500cc/24hours versus liberal fluid intake for a period of 3 months.

Study burden and risks

Participants will be recruited and followed at the specialized HF outpatient clinic according to standard clinical practice with a 3-month interval including standard laboratory analyses (renal function, electrolytes, NT-proBNP). Subjects will be randomized for 3 months to an advice of either liberal fluid intake or fluid restriction of 1500cc/24hours, of which the latter is current standard clinical practice. At baseline and after 3 months, participants will be asked to fill out a QoL questionnaire. In addition, subjects will be asked to report their daily fluid intake at week 6. In terms of benefits and risks, fluid restriction in HF leads to an undesirable sensation of thirst. For patients with HF, thirst can be distressing and can decrease quality of life. There is no evidence that fluid restriction reduces symptom burden or adverse events such as HF hospitalizations due to fluid retention, whereas liberal fluid intake may result in increased quality of life due a decrease in thirst. Given the vast target population of chronic HF patients worldwide, and the simplicity of the intervention, potentially millions of HF patients may benefit from the results of this study.

Contacts

Public

Radboud Universitair Medisch Centrum

Geert Grooteplein 10

Nijmegen 6525GA

NL

Scientific

Radboud Universitair Medisch Centrum

Geert Grooteplein 10

Nijmegen 6525GA

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Diagnosis of chronic heart failure according to the prevailing guidelines > 6 months prior to randomization
- Adult (age ≥ 18 years)

Exclusion criteria

- Reversible cause of HF (thyroid disorders, severe anemia, vitamin deficiencies)
- Hospital admission for HF within 3 months of randomization
- Hyponatremia at baseline (sodium $<130\text{mmol/l}$)
- Estimated Glomerular Filtration Rate (eGFR) of $< 30\text{ml/min/1.73 m}^2$ at baseline
- Changes in HF medical therapy in last 14 days prior to randomization
- Scheduled cardiac surgery within 3 months of randomization
- Comorbidity for which fluid restriction is advised by a different treating physician (e.g. nephrologist)
- Inability to provide informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	17-05-2021
Enrollment:	506
Type:	Actual

Ethics review

Approved WMO	
Date:	26-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	23-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	02-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	21-06-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-12-2022
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	10-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	05-06-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT04551729
CCMO	NL75112.091.20