effectiveness of low-salt bread on the total sodiumintake in patients with chronic heart failure

Published: 09-12-2015
Last updated: 20-04-2024

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

Summary

ID

NL-OMON45077

Source
ToetsingOnline

Brief title
LoSa Pilot Study

Condition

- Heart failures

Synonym
chronic heart failure. heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: bedrijf ,Scelta Mushrooms

Intervention

Keyword: bread, heart failure, low-salt

Outcome measures

Primary outcome

The main study parameter is a reduction in daily salt intake, which will be measured by detection of sodium in the urine. There will also be a comparison with the food frequency questionnaire which the patients collect during several days. Our primary hypothesis is that a low sodium intake due to the low sodium bread will lead to an improvement of our secondary study parameters

We expect a reduction of daily salt intake of 1.5 gram sodium by an average of 5 slices bread a day.

Secondary outcome

Secondary study parameters will be:

- Blood pressure

- Protein in the urine

- Quality of life

- Body weight

- Signs of heart failure - NYHA classification

- body composition and fluid status (intra en extra cellulair) (this measurement will not be performed in patients wit a pacemaker or ICD)

Study description

Background summary

Patients with heart failure may suffer from a poor quality of life (QoL) due to frequent hospital admittance, medication intake and as a result of symptoms and progression of their disease. The general salt intake in the Dutch population is too high, which can indirectly lead to cardiovascular disease such as heart failure and renal failure. Patients with heart failure are highly salt sensitive.
The aim of this study is to lower the daily salt intake by providing a palatable low salt bread to patients with heart failure. This may lead to a stable disease and therefore an improvement of quality of life.

Study objective

The aim of this pilot study is to investigate whether substitution of normal bread by a new palatable form of low salt bread is effective in reducing the daily salt intake in patients with CHF. Furthermore the influence of the presumed salt reduction on body composition, body weight, protein in urine and blood pressure will be measured.

The following research questions will be evaluated:
1. Effectiveness: Does low salt bread reduce the daily salt intake?
2. Compliance: Is low salt bread tolerated?
3. Outcome: What is the effect of low salt bread on body-composition, blood pressure and bodyweight, quality of life, protein in the urine?

Primary objective is the reduction in salt intake, by measuring the 24-h urine sodium excretion. The secondary objectives are the effects of a lower salt intake on blood pressure measured during 15 minutes, symptoms of heart failure (dyspnoea, oedema, NYHA class), proteinuria, body composition and feasibility of a new developed tasty low-salt bread.

Study design

This Pilot study will be a randomized single-centre cross-over study, performed at the department of Cardiology of the VieCuri Medical Centre. The study has to be approved by the Maastricht University Medical Centre METC.
After approval by MUMC Medical Ethical Committee the institutional ethics committee of Viecuri MC will evaluate the feasibility of the study.

Study design:
After baseline measurements (primary aetiology of disease, age, height, weight, BMI, medication) are taken, participants will be counseled to follow a regular low-sodium diet (goal 80-100 mmol = 5-6 gram salt) as normally performed in the interest of the patients disease. Dietary education will be individualized to the participant' s food preferences and was provided by an accredited

practicing dietitian.

After including 20 patients with heart failure, an interim analysis will be performed to evaluate the feasibility of significant differences and sample size re estimation if needed.

After a two-week run-in period on a low-sodium diet, participants will be randomized to the normal bread consuming group or the low salt bread group. After the six week follow up (continued with the general low-sodium diet), patients cross over to the other intervention group.

Participants, investigators, and outcome assessors will be blinded to the allocation.

Intervention

29 Patients receive a low salt bread (0.1 gram sodium per slice) and another 29 patients receive bread with a normal amount of sodium (0.4 gram sodium per slice). After six weeks follow up, the groups change the intervention.

Participants will be informed about the low salt diet for patients with heart failure. After this, they will be randomized in the different intervention groups:
- Group 1: will receive the Scelta bread with a normal amount of sodium (0.4 gram Sodium)
- Group 2: will receive the Scelta bread with a low amount of sodium (0.1 gram Sodium).

Study burden and risks

Patients should visit the hospital three times. During all visits blood samples will be taken and a physical exam is performed. Prior the hospital visit they have to collect urine during 24hour. Also a 15 minutes blood pressure will be measured. Most of these parameters will also be collected for regular clinical-care purposes. Patients should also report their daily intake in a personal food diary and fill in questionnaires about their opinion of the bread and quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age at least 18 years;
Estimated GFR (based on Modification of Diet in Renal Disease (MDRD) calculation) 15-45 ml/min/1.73m2, not receiving RRT
CHF NYHA III-IV, stable condition on optimal medical therapy: no medication changes in last two weeks prior to start study.
Written informed consent
Speak and read Dutch

Exclusion criteria

Pregnancy or breastfeeding
Participating in any other interventional research study during the same period
Hyponatremia; sodium < 130 mmol/L
Cognitive impairment
Blood pressure systolic below 110 mmHg or diastolic below 50 mmHg
Allergic reaction to mushrooms, silica , corn and gluten
Patients were excluded in the follow up period when diuretics were adjusted.
Hyper/hypo phosphatemia, potassium

Life expectancy shorter than 1 year
Suffering from a salt loosing nephropathy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2018
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL47820.068.14