Glycocalyx restoration in chronic heart failure: a proof of concept, randomized, double-blind, placebo-controlled study

Published: 27-10-2022
Last updated: 06-05-2024

To assess the efficacy of treatment with Endocalyx for chronic heart failure.

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

Summary

ID

NL-OMON51489

Source
ToetsingOnline

Brief title
Endocalyx for heart failure (GLYCO-HF)

Condition

- Heart failures

Synonym
Heart failure with reduced ejection fraction (HFrEF)

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: glycocalyx, glycosaminoglycans, heart failure, non-osmotic sodium storage

Outcome measures

Primary outcome

Percent change of NT-proBNP from baseline to week 8

Secondary outcome

Bloodpressure

Hemodynamic parameters

Fluid status

Monocyte subsets

Monocyte surface proteins

Quality of life

Distance covered during six minute walking test

Incidence of (serious) adverse events.

Study description

Background summary

Chronic heart failure is characterized by sodium and water overload despite lifestyle advices and drug therapy. The endothelial surface layer (ESL) is able to neutralize the negative effects of sodium excess such as water retention and high blood pressure. The ESL is damaged in heart failure patients. Restoration of the ESL with Endocalyx, an oral supplement consisting of ESL constituents, is therefore hypothesized to lower sodium and water excess in heart failure patients.

Study objective

To assess the efficacy of treatment with Endocalyx for chronic heart

failure.

Study design

A proof-of-principle randomized, placebo-controlled, double blind trial

Intervention

Endocalyx (total of 4 capsules per day; twice per day 2 capsules or once daily 4 capsules) for 8 weeks versus placebo once daily for 8 weeks. There will be a follow up studyvisit in week 12.

Study burden and risks

Subjects need to take the study supplements daily for eight weeks. The study supplements are already available online in the United States and to date no major side effects have been reported.

There will be a total of 5 study visits. A 24-hour blood pressure measurement will be performed, and 24-hour urine will be collected, three times. Blood will be sampled, four times, with a total volume of 100mL. All subjects will be asked to fill in a questionnaire, 3 times. Several non-invasive measurements, including office blood pressure and micorcirculation measurements, will be performed.

A total of 16 subjects will be approached for a total of 4 (invasive) skin biopsies. This will only be performed if the subject has given consent for the biopsies.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Chronic heart failure with reduced ejection fraction (HFrEF)
- Elevated NT-proBNP and signs of congestion (e.g. use of diuretics, peripheral edema)
- Stable diuretic and antihypertensive treatment

Exclusion criteria

Estimated glomerular filtration rate (eGFR) <15 ml/min/1.73m2
- Systolic (<105 mmHg) or diastolic hypotension (<60 mmHg)
- A cardiovascular event in the last 3 months.
- Hospitalization for heart failure in the past 3 weeks or major surgery in the previous 4 weeks.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2023
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO

Date:	27-10-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL81588.018.22