Pancreatic exocrine insufficiency in heart failure

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Primary Objective: The primary objective of this study is to investigate the prevalence EPI in the advanced HF population Secondary Objectives: • To determine the association between exocrine pancreatic function and markers of HF• To determine the...

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

Summary

ID

NL-OMON50432

Source
ToetsingOnline

Brief title
PEXI-HF

Condition

- Heart failures
- Appetite and general nutritional disorders

Synonym
Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: afdeling cardiologie UMCG

Intervention

Keyword: Cardiac cachexia, Exocrine pancreas insufficiency, Heart failure, Malnutrition

Outcome measures

Primary outcome

The prevalence of EPI (defined as FE-1 <200 µg/g) in the advanced HF population compared to controls with mild HF

Secondary outcome

• The association between FE-1 results and natriuretic peptides (NT-proBNP)

• The association between FE-1 results and patient-reported outcome related to HF

• The association between FE-1 results and vitamin status

• The association between FE-1 results and patient-reported outcome related to loss of appetite/malnutrition

• The association between FE-1 results and the prevalence of significant weight-loss (defined as loss of >5% body weight the past 6 months)

Study description

Background summary

Heart failure (HF) is a complex clinical syndrome resulting from any functional or structural heart disorder, impairing ventricular filling or ejection of blood to the systemic circulation to meet the systemic needs [1,2]. Hemodynamically this results in congestion and/or hypoperfusion, and a widespread neurohormonal and inflammatory response. Ultimately this leads to impairment and/or failure of target organs, of which the kidney [3,4], liver [5,6], brain [7,8] and intestines [6,9,10] have been widely studied. The influence of these hemodynamic perturbations on the pancreas, however, has not been well documented. This is striking, given the high degree of congestion in the abdominal compartment [11], the susceptibility of the pancreas to ischemia

[12-15] and increased venous pressures [12] and the prevalence of malnutrition and appetite loss among the (advanced) HF population.

The pancreas is principally an exocrine gland, responsible for discharging digestive enzymes and bicarbonate into a system of intercalated ducts emptying into the proximal duodenum. There seems to be an age-dependent decline in exocrine pancreatic parenchyma, which is likely related to decreased perfusion [16]. Although studies are scarce, HF also seems to lead to exocrine pancreatic insufficiency (EPI) [13,17]. EPI results in maldigestion and malnutrition, which in patients with (advanced) HF, could aggravate the development and consequences of cardiac cachexia, a hallmark and strong independent prognostic factor [18-20]. Unfortunately, no studies on the prevalence and consequences of EPI in the advanced HF population, who are most susceptible to pancreatic injury and cardiac cachexia, exist.

It is hypothesized HF is associated with pancreatic congestion leading to exocrine pancreatic insufficiency (EPI) and this in turn contributes to loss of appetite and the syndrome of cardiac cachexia [21]. The aim of this study is to investigate EPI in the HF population and to determine its association with markers of congestion and appetite loss. The results would increase our understanding of HF-related target organ impairment and contribute to therapies such as dietary intervention or pancreatic enzyme supplementation in the HF population.

Study objective

Primary Objective:
The primary objective of this study is to investigate the prevalence EPI in the advanced HF population

Secondary Objectives:
• To determine the association between exocrine pancreatic function and markers of HF
• To determine the association between exocrine pancreatic function and patient-reported outcome related to HF
• To determine the association between exocrine pancreatic function and vitamin status
• To determine the association between exocrine pancreatic function and loss of appetite
• To determine the association between exocrine pancreatic function and the prevalence of weight-loss

Study design

The current study is a single center, cross-sectional, case-control observational study. A total of 30 patients diagnosed with chronic advanced HF

at the University Medical Center Groningen (UMCG) cardiology department will be recruited. These patients are matched for sex and age with 30 controls with mild HF. This study will be performed at the outpatient clinic and the wards of the UMCG department of cardiology.

Study burden and risks

Participants are burdened with additional blood sampling through vena puncture. Additionally, participants are burdened with non-invasive fecal sampling and testing and administration of patient-reported outcome measures.
There are no significant risks associated with this study.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

(1) age >= 18 years
(2) give written informed consent
(3) the Heart failure group must fulfil the ESC criteria for advanced heart failure. In the control group heart failure must be considered mild (NYHA class I/II, AHA stage C)

Exclusion criteria

(1) pancreatic diseases, including acute pancreatitis, chronic pancreatitis and pancreatic cancer
(2) chronic liver disease and/or severe liver dysfunction with ASAT and/or ALAT > 3x the upper limit of normal (ULN)
(3) congenital metabolic disease
(4) cystic fibrosis
(5) inflammatory bowel disease
(6) irritable bowel disease
(7) history of gastric bypass surgery
(8) pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2022
Enrollment:	60

Type:	Actual

Ethics review

Approved WMO Date:	29-11-2021
Application type:	First submission
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
CCMO	NL78998.042.21