Pancreatic exocrine functioning after cardiac resynchronization therapy

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Primary Objective: 1. To investigate the effect of CRT on markers of pancreatic exocrine functioningSecondary Objectives: 1. To compare changes in markers of pancreatic exocrine function between CRT responders and non-responders2. To compare the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON50583

Source
ToetsingOnline

Brief title
PEX-CRT

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 resynchronization therapy, Exocrine pancreas insufficiency, Heart failure, Malnutrition

Outcome measures

Primary outcome

The change in FE-1 results and markers of nutritional status at baseline and

6-months after CRT implantation

Secondary outcome

1. The (change in) FE-1 results between CRT responders and non-responders

2. The difference in prevalence of exocrine pancreatic insufficiency (defined

as FE-1<200 pg/g) between CRT responders and non-responders

3. The association between exocrine pancreatic insufficiency (defined as FE-1

<200 pg/g) at baseline and response to CRT

4. The association between the degree of response (change in LVESV) and change

in FE-1

Study description

Background summary

Heart failure (HF) is a 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). 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 well studied. In contrast, the effects of the hemodynamic derangements of HF on the pancreas have received little attention. This is surprising, given the pancreas is particularly susceptible to ischemic injury (11-14) and congestion (15,16). Although conclusive data are lacking, HF is thought to result in exocrine pancreatic insufficiency (17), potentially leading to further deterioration through maldigestion and malnutrition.

Cardiac resynchronization therapy (CRT) is an effective method to treat HF with reduced ejection fraction (HFrEF) accompanied by ventricular dysschrony (18). CRT improves cardiac efficiency through better temporal coordination of left ventricular activation and contraction, resulting in increased cardiac output and stroke work and reduced mitral regurgitation and cardiac filling pressures (19-22). CRT exerts systemic hemodynamics leading to increased survival, lower HF-related hospitalization and improved end-organ functioning (23,24). Unfortunately, approximately one-third of recipients fail to respond to CRT for a variety of reasons (25-27).

Non-response to CRT is reflected by little hemodynamic improvement and potentially further deteriorating clinical status and end-organ function. Ideally, CRT mitigates end-organ dysfunction through both improved perfusion and reduced venous pressures (22,28,29). This has previously been demonstrated through improved renal function after CRT, which has shown to be indicative of response to therapy (22,30,31). Other organ systems also seem to respond to therapy (32,33), yet are underreported in current scientific literature.

The rapid hemodynamic changes induced by CRT make it an interesting intervention to study the effects of HF on the pancreas. Given the proposed susceptibility of the (exocrine) pancreas to hemodynamic variations (11-16), it is hypothesized favourable response to CRT is reflected by improved exocrine pancreatic function. The aim of this study is to investigate the effect of CRT on pancreatic exocrine functioning and to compare CRT responders and non-responders.

Study objective

Primary Objective:
1. To investigate the effect of CRT on markers of pancreatic exocrine functioning

Secondary Objectives:
1. To compare changes in markers of pancreatic exocrine function between CRT responders and non-responders
2. To compare the prevalence of exocrine pancreatic insufficiency between CRT responders and non-responders
3. To investigate the association between exocrine pancreatic insufficiency at baseline and response to CRT
4. To investigate the association between the degree of response to CRT and changes in markers of pancreatic exocrine functioning

Study design

This is a single center, prospective observational study performed at the University Medical Center Groningen (UMCG). A total of 60 patients referred to

our center for transvenous CRT implantation will be recruited.
The standard CRT protocol in our center consists of blood sampling, electrocardiography, and radiographs at baseline and evaluation of response at 6 months after implantation.

Study burden and risks

Participants are burdened with non-invasive faecal sampling testing at baseline and 6-months after CRT implantation. The present study may render important insights into the effects of HF on the pancreas. Additionally, this study may provide insight into the utility of pancreatic testing to identify response to CRT.

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

(1) age >= 18 years
(2) accepted for de novo transvenous CRT-(D/P) implantation at the UMCG for chronic heart failure
(3) give written informed consent

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 non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	01-02-2022
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	NL79324.042.21