# Changes of the myocardium in heart failure with preserved ejection fraction: unravelling the role of epicardial adipose tissue

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To assess the inflammatory secretome of EAT, its subsequent interaction with cardiomyocytes, and its potential implication in the development of LV diastolic dysfunction.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Heart failures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56541

**Source**
ToetsingOnline

**Brief title**
COMPEAT

### Condition

- Heart failures

**Synonym**
heart failure, reduced functioning of the heart

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** epicardial, heart failure, HFpEF, obesity

## Outcome measures

### Primary outcome

The main study parameters are EAT-mediated inflammatory biomarkers and their association with clinical parameters for HFpEF, as well as their interaction with cardiomyocyte/endothelium structure and/or function.

### Secondary outcome

The secondary study paramaters are:

- Differences in inflammatory markers between EAT and subcutaneous adipose tissue (EAT) samples and secretomes

- Inflammatory biomarkers in plasma and the different with nflammatory biomarkers in EAT samples

# Study description

### Background summary

The incidence of heart failure with preserved ejection fraction (HFpEF) continues to rise at an alarming rate, and to date effective treatments are severely limited. Patients with HFpEF suffer from high morbidity and mortality due to left ventricular (LV) diastolic dysfunction with consequently increased filling pressures of the heart. Additionally, most patients suffer from comorbidities such as hypertension, metabolic disease, and obesity.

Obesity has been identified as a key player in the pathophysiology of HFpEF. Multiple studies have demonstrated a strong correlation between accumulation of epicardial adipose tissue (EAT) and worse clinical outcomes. Furthermore, EAT is suggested to drive structural and functional impairments of the myocardium, mainly through activation of inflammatory pathways.

### Study objective

To assess the inflammatory secretome of EAT, its subsequent interaction with cardiomyocytes, and its potential implication in the development of LV diastolic dysfunction.

### Study design

Observational study

### Study burden and risks

EAT and subcutaneous adipose tissue (SAT) that are retrieved during elective cardiac (open-heart) surgery anyway, will be collected. EAT is normally removed from different locations (e.g. ventricular free wall, right atrial appendage) to improve access to the heart and/or coronary arteries during the surgery. Additionally, the surgeon typically removes some SAT at the site of incision to facilitate access to the heart. In both situations, EAT and SAT are normally disposed of as surgical waste. For this study, we would like to use the already retrieved EAT and SAT for further processing. Since the tissue is separated and collected anyway as part of the procedure, there are no additional risks involved.
Additionally, we would like to collect some extra blood samples during routine blood collection prior to the surgery

## 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

- Patients undergoing elective cardiac surgery with cardiopulmonary bypass
- Legally competent, willing, and able to sign informed consent

### Exclusion criteria

- Hemodynamically stable, no inotropic/vasopressic and/or mechanical support prior to surgery.
- Active infection or inflammation, e.g. endocarditis, pericarditis
- Chronic use of anti-inflammatory medication, e.g. steroids;
- Age <18 years

## 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: | Pending |
| Start date (anticipated): | 01-02-2024 |
| Enrollment: | 400 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Registration: | No |

## Ethics review

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|---|---|
| Approved WMO Date: | 14-02-2024 |
| 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 | NL85954.018.23 |