Pericardial Tissue and the Post Pericardiotomy Syndrome

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1. To get new insights in the pathophysiology of PPS by comparing tissue characteristics (histology) of the pericardium in patients with and without PPS. 2. To identify biomarkers that are associated with PPS by collecting 4 blood- and 1 pericardial...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pericardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON44142

Source
ToetsingOnline

Brief title
Pericardial tissue and PPS

Condition

- Pericardial disorders
- Cardiac therapeutic procedures

Synonym
postpericardial injury syndrome; Dressler syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pericardial tissue, Post Pericardiotomy Syndrome

Outcome measures

Primary outcome

1. The following histology studies of pericardial tissue in patients with and

without PPS will be performed:

- Hematoxylin and eosin staining (HE stain)

- CD3, CD20 and CD68 staining (to identify macrophages, T- and B-lymphocytes)

- General description of findings by the pathologist.

2. Diagnosing PPS

Secondary outcome

To assess biomarkers that are associated with PPS by collecting 4 blood- and 1

pericardial fluid samples. The material will be stored in the central biobank

of the UMC Utrecht, because at this time it is unclear which biomarkers should

be investigated. This also depends partially on findings at histology studies.

Study description

Background summary

Post Pericardiotomy Syndrome (PPS) is a common complication of cardiac surgery (10-20%) and is characterized by postoperative pericardial and pleural effusions. The syndrome is associated with serious postoperative problems such as cardiac tamponade. Inflammation is a possible etiologic factor, however the exact pathogenesis and thus optimal treatment and prevention strategies, remain unclear. Histology studies of PPS have never been performed before and may provide new information about the pathophysiology of PPS.

Study objective

1. To get new insights in the pathophysiology of PPS by comparing tissue characteristics (histology) of the pericardium in patients with and without PPS.
2. To identify biomarkers that are associated with PPS by collecting 4 blood- and 1 pericardial fluid sample in all study patients (ca. 40 patients). The material will be stored in the central biobank of the UMC Utrecht, because at this time it is unclear which biomarkers should be investigated. This also depends partially on findings at histology studies.
3. To get new insights in changes in tissue characteristics after cardiac surgery by comparing tissue characteristics of the pericardium in patients undergoing initial cardiac surgery and in patients undergoing a rethoracotomy.

Study design

This study is designed as a case-control study. In all adult (*18 years) patients undergoing a full resternotomy for any reason (24 hours after initial surgery, but within 90 days after initial cardiac surgery), a small tissue sample of the pericardium, a peripheral blood sample and a pericardial fluid sample will be obtained. In case of a subxiphoid or lateral rethoracotomy, it is not possible to obtain a pericardial tissue sample, therefore only a blood- and pericardial fluid sample will be obtained in this category of patients.
We will retrospectively examine whether the patients who underwent a resternotomy had PPS before the resternotomy or not by examining all the perioperative echocardiograms, chest X-rays and medical records. This will be done by two independent investigators. Pericardial tissue characteristics of the two groups (PPS vs. no PPS) will be analyzed by an investigator who is blinded for the diagnosis PPS to minimize the chance of observer bias.
Furthermore, in 10 adult patients undergoing isolated valve surgery (5 patients) or isolated CABG (5 patients) for the first time, peripheral blood, a pericardial tissue sample and pericardial fluid will be obtained. The patients will be followed during the postoperative phase (until discharge) to determine whether they develop PPS or not. Also a second pericardial fluid sample will be taken on day 3 postoperatively from the pericardial drain (or, if earlier, directly before the drain is removed). Tissue characteristics will be compared between the groups (PPS vs. no PPS). All pericardial fluid and blood that is obtained in the study, will be saved in the Central Biobank of the UMCU to investigate biomarkers that are associated with PPS in the future.

Study burden and risks

Because the pericardium is already opened by the surgeon in all the patients, obtaining a small pericardial tissue sample is very unlikely to increase the risk of the operation. Multiple studies showed that taking percutaneous pericardial biopsies is safe. A sternotomy might be even safer because the fact

that the surgeon has the pericardium in sight. Also, in thoracic surgery, it is daily practice to use parts of the pericardium to close operation defects. This is considered safe by thoracic surgeons and is not known to be associated with complications afterwards. The participants will not benefit directly from participating in the study, but it might help the group (patients at risk of PPS) in the future.

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) For rethoracotomy patients:
- Adult (*18 years) patients undergoing a rethoracotomy for any reason, within 90 days after initial cardiac surgery.;2) For patients undergoing a first sternotomy:
- Adult (*18 years) patients undergoing an isolated CABG (5 patients) or isolated valve

surgery (5 patients) via a full sternotomy for the first time.

Exclusion criteria

1) For patients undergoing a rethoracotomy:
- Patients undergoing a rethoracotomy within 24 hours after initial cardiac sugery (24 hours after the first incision)
- Patients undergoing pericardial surgery (pericardial window or pericardiectomy) as initial surgery because of recurrent pericardial fluid or a pericardial disease.
- Patients undergoing a heart transplantation as initial surgery (because of the routine use of anti-inflammatory agents postoperatively)
- Patients undergoing a LVAD implantation as initial surgery
- Patients undergoing valve replacement as initial surgery because of endocarditis
- Patients with a medical history of pericarditis
- Patients with a medical history of auto-immune disease and who use corticosteroids on a daily basis;2) For patients undergoing a first sternotomy:
- Patients undergoing an emergency operation
- Patients with a medical history of pericarditis
- Patients with a medical history of auto-immune disease and who use corticosteroids on a daily basis
- Patients with endocarditis
- Patients with pericardial effusion on the preoperative echo.

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):	10-06-2016

Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL54644.041.16

Study results

Date completed:	10-01-2019
Actual enrolment:	40