

Postoperative infections a potential modifiable risk factor for non-recovery in physical health-related quality of life one year after cardiac surgery?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20083

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Cardio-thoracic diseases that require surgery

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Postoperative Infection is a risk factor for lack of physical recovery 1 year after cardiac

surgery

Secondary outcome

Interrelationship between different predictors diabetes mellitus, re-PCI, and postoperative infections on the lack of physical recovery 1 year after surgery

Study description

Background summary

A recent single-center study, based on Dutch Heart Registry (NHR) data, showed that the occurrence of any postoperative infection after cardiac surgery was independently associated with a reduced chance of physical recovery 1 year after surgery (21% of all patients with no postoperative infection did not improve in physical function after one year versus 37.8% of all patients with a postoperative infection). This suggests that the occurrence of postoperative infections can have a significant impact on the well-being of patients and that such an undesirable course could potentially be prevented. Therefore, the goal of this study is to evaluate if these findings can be reproduced in the Dutch Heart Registry dataset and to clarify the interrelationship between this independent risk factor of non-recovery and other independent risk factors as diabetes and coronary re-intervention.

Study objective

- 1/2. Postoperative infections are a risk factor that negatively interferes with physical recovery 1 year after cardiac surgery. It is expected that propensity scoring techniques will provide a more accurate ("unbiased") estimate of the effect of the occurrence of an infection on the lack of physical recovery, making it more likely that this is a possible causal association.
3. Patients with diabetes mellitus are more likely to get a postoperative infection. The lack of physical recovery in patients with diabetes mellitus is stronger than in patients without diabetes mellitus. In addition, it is expected that the effect of infections on the lack of physical recovery is partly due to an increased risk of re-intervention (re-PCI or re-CABG) (as a proxy for atherosclerosis).
4. In women, the negative effect of postoperative infections on the lack of physical recovery is expected to be more pronounced.
5. The type of hospital infection won't be of any influence on the above mentioned associations.

Study design

Baseline questionnaire (T0) and 1 year follow up questionnaire (T1)

Intervention

N/A

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

1. All patients scheduled for an elective or urgent cardio thoracic surgical procedure between 01-01-2015 and 01-01-2020.
2. Age: 18 years and older.
3. SF 36 (version 2) or SF 12 (version 2) measurement was performed both before and 1 year after the cardiothoracic intervention. At least 50% of the questions of each domain had to be filled in when using the SF-36 and 100% when using the SF-12.

Exclusion criteria

1. Aborted interventions, after a skin incision or puncture has taken place.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2021
Enrollment:	7993
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	22-10-2021
Application type:	First submission

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

NTR-new NL9818

Register ID

Other Regionale Toetsingscommissie Patiëntgebonden Onderzoek, Leeuwarden, the Netherlands : RTPO 1120

Study results

Summary results

N/A