

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20083

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

Cardio-thoracic diseases that require surgery

Ondersteuning

Primaire sponsor: N/A

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Contactpersonen

Publiek

Medisch Centrum Leeuwarden
Hilda Rijnhart-de Jong

058-2863976

Wetenschappelijk

Medisch Centrum Leeuwarden
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	22-10-2021
Aantal proefpersonen:	7993
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	22-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9818
Ander register	Regionale Toetsingscommissie Patiëntgebonden Onderzoek, Leeuwarden, the Netherlands : RTPO 1120

Resultaten

Samenvatting resultaten

N/A