# INFLAMMATORY INJURY of the LUNG after CARDIAC SURGERY

No registrations found.

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

# **Summary**

### ID

NL-OMON24292

Source NTR

Brief title

**Health condition** 

ARDS, Lung injury, Cardiac Surgery, CPB, Ivflammatory response

### **Sponsors and support**

Primary sponsor: none
Source(s) of monetary or material Support: fund = initiator = spons

#### Intervention

### **Outcome measures**

#### **Primary outcome**

Length of ICU-stay, length of hospital-stay, ICU-mortality, 30-day mortality

## Secondary outcome

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1. Prognostic: occurrence of ALI and ARDS, duration of mechanical ventilation, need for renal replacement therapy

2. Etiologic: levels and time course of markers of inflammation and ischemia-reperfusion in relation to the clinical course (such as All and ARDS, duration of mechanical ventilation, need for renal replacement therapy, ICU-stay, hospital-stay, ICU-mortality, 30-day mortality) particular in patients following complex heart surgery as opposed to low risk surgery

3. Methodologic: Investigate the value of collecting minimal invasive endobronchial samples in cardiac surgery patients.

# **Study description**

#### **Background summary**

After cardiac surgery an inflammatory response develops, due to cardiopulmonary bypass (CPB) and ischemia-reperfusion injury. This response is more pronounced in patients with pre-existent heart failure. Due to this response, injury of several organs develops, leading to a complicated course and a prolonged stay at the intensive care. Particularly, when injury of the lung develops, ventilation time increases, associated with a raise of mortality up to 25 % in certain patient-groups. The causes of this lung injury are multifactorial: partly secondary to filtration of inflammatory factors due to ischemia-reperfusion of other organs, partly secondary to absence of ventilation during CPB and finally secondary to ischemia reperfusion of the lung since solely arterial bronchialis perfusion is insufficient to provide the complete metabolic needs of the lung. But up to now full details on the pathogenesis of lung injury post CPB are unknown.

Study objective.

It is our aim to predict the clinical course (in terms of occurrence of ALI and ARDS, duration of mechanical ventilation, need for renal replacement therapy, length of ICU-stay, length of hospital-stay, ICU-mortality, 30-day mortality) in patients after cardiac surgery. In addition to demographic and clinical prognostic parameters, the focus will be on the additional prognostic ability of markers of inflammation and ischemia reperfusion injury, of genetic predisposition and of measures of gene-expression to predict the clinical course following cardiac surgery.

Furthermore, in light of the already available knowledge on inflammatory and ischemiareperfusion markers, we aim to explain the clinical course of patients after complex and low risk cardiac surgery in relation to the inflammatory and ischemia-reperfusion response, particular occurring in the lung. Endpoints of the Study.

Primary endpoints: Length of ICU-stay, length of hospital-stay, ICU-mortality, 30-day mortality Secondary endpoints:

1. Prognostic: occurrence of ALI and ARDS, duration of mechanical ventilation, need for renal replacement therapy

2. Etiologic: levels and time course of markers of inflammation and ischemia-reperfusion in relation to the clinical course (such as ALI and ARDS, duration of mechanical ventilation, need for renal replacement therapy, ICU-stay, hospital-stay, ICU-mortality, 30-day mortality) particular in patients following complex heart surgery as opposed to low risk surgery

3. Methodologic: Investigate the value of collecting minimal invasive endobronchial samples in cardiac surgery bypass patients.

#### Study objective

Inflammatory injury of the lung after cardiac surgery in heart failure versus non-heart failure patients; An observational study of clinical variables, genetic association, and etiologic and prognostic aspects of inflammatory markers in serum and endobronchial samples in patients with pulmonary injury after cardiac surgery.

#### Study design

follow up period 30 days

#### Intervention

none

# Contacts

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# **Eligibility criteria**

# **Inclusion criteria**

All adult patients, that are scheduled for all types of elective cardiac surgery, with or without CPB. For the purpose of the study low risk cardiac surgery is defined as CABG with single valve reconstruction or replacement. Complex cardiac surgery is defined as: multiple valves reconstruction or replacement, and/or heart failure surgery (DOR, corcap)

## **Exclusion criteria**

Inability to sign informed consent, less than 18 years old, emergency operations

# Study design

## Design

Study type:Observational non invasiveIntervention model:FactorialAllocation:Non controlled trialMasking:Open (masking not used)Control:N/A , unknown

### Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011

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Enrollment:

Type:

160 Anticipated

# **Ethics review**

Positive opinionDate:26-05-2015Application 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	NL5174
NTR-old	NTR5314
Other	MEC LUMC leiden : p11-117

# **Study results**

Summary results none