Inflammatory injury of the lung after cardiac surgery

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1. 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON41450

Source
ToetsingOnline

Brief title
INFLAME

Condition

- Heart failures
- Respiratory disorders NEC
- Cardiac therapeutic procedures

Synonym
Acute Lung Injury, Inflammatory induced pulmonary Injury

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: er is vooralsnog geen financieringsregeling

Intervention

Keyword: Cardiac Surgery, Heart failure, Inflammatory, Lung injury

Outcome measures

Primary outcome

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

Secondary outcome

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 AII 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

Rationale
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 ischemia-reperfusion injury of the lung develops, ventilation time increases, associated with a raise of mortality up to 25 % in certain patient-groups. But up to now only few details of pathogenesis of this lung damage is known.

Study objective

1. 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.
2. To explain, in light of the already available knowledge on inflammatory and ischemia-reperfusion markers, 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.

Study design

The study is designed as a single centre prospective observational cohort study

Study burden and risks

Patients will be treated according to routine care. Intravenous and arterial access is available in all patients, since this is routine care in the thoracic patient group. Furthermore endobronchial samples will be taken during routine suctioning moments and only in intubated patients. Urine samples will be taken fram the urinary catheter. The total amount of blood necessary will be utmost 210 cc. The extent of the burden will be very low and the risk associated with paticipation is nihil.

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

Adult patients scheduled for cardiac surgery

Exclusion criteria

minor
ermergency surgery
not able to sign informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011

Enrollment:	250
Type:	Actual

Medical products/devices used

Generic name:	combicath mini BAL catheter;58216.27 Pe 60 cm x 2;7mm;CE 0120
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-09-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-07-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL36267.058.11

Study results

Date completed:	01-01-2018
Actual enrolment:	120