The effects of high oxygen levels on circulation during and after cardiac surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27282

Source
NTR

Health condition

hyperoxia, cardiac surgery, myocardial damage, ROS, oxidative stress

Sponsors and support

Primary sponsor: VU University Medical Center,
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Intervention

Outcome measures

Primary outcome

Myocardial damage (CK-MB, hs-troponine-T)

Secondary outcome

Hemodynamic parameters: SVRI and C.I.
microcirculation
oxidative stress
tissue/organ perfusion
clinical endpoints (duration of mechanical ventilation, length of stay, mortality).

Study description

Background summary

Rationale: Although the deleterious effects of hypoxia are well known, most physicians are less aware of the potential harmfull effect of hyperoxia. To avoid hypoxia, the tendency to supply extra oxygen to patients is widespread. Increasing evidence shows that hyperoxia has important circulatory effects, with decreased cardiac output (CO) and increased systemic vascular resistance (SVR), resulting in increased infarct size and increased mortality after myocardial infarction and cardiac arrest. The underlying mechanisms are unknown, but could relate to increased formation of reactive oxygen species (ROS), which not only causes vasoconstriction, but also other untoward effects, such as reperfusion damage.
Hyperoxia is frequently, >20% of the mechanical ventilation time, encountered in the Intensive Care. Patients who underwent a coronary bypass graft operation (CABG) may be especially vulnerable to the detrimental cardiovascular effects of hyperoxia because of fluctuations in cardiac function due to other causes (such as blood loss and fluid shifts) post-surgery. However, many physicians still feel that increased arterial oxygen pressure (PaO2) represents a salutary oxygen reserve not only post-surgery but also during cardiopulmonary bypass (CPB). PaO2 measurements of >200 to 300 mmHg during CPB are no exception, as confirmed by our own pilot data. Therefore, we chose to investigate the cardiovascular effects of hyperoxia in patients during and after CABG surgery together with the proposed mechanisms by which hyperoxia exerts its effects. We will compare standard patient care, using supra-normal PaO2 levels, with oxygen levels titrated to a (near) normal physiological range.
We hypothesize that hyperoxia during and post CABG surgery has unfavourable effects on hemodynamics, microcirculation, and ischemia/reperfusion injury, due to increased oxidative stress (ROS) affecting endothelium-derived vaso-active factors.

Objectives:
1. To study the effect of different target PaO2's on myocardial injury, hemodynamics, microcirculation and organ perfusion injury in CABG patients.
2. To study underlying mechanisms of hyperoxia by determining differences in oxidative stress response between the hyperoxic patients and the normoxemic groups.

Study design: Randomized, prospective clinical trial
Study population: Patients undergoing CABG surgery
Intervention: We will investigate current practice (1, 2; group I) with (near) normal oxygen levels (group II).

group I: target PaO2 on CBP during aortic clamp time 200 ¨C 220 mmHg, PaO2 at ICU of 130-150 mm Hg
group II: : After intubation FiO2 will be decreased to 40% (provided that O2 saturation remains > 96%). Target PaO2 on CBP during aortic clamp time 130 ¨C 150 mmHg, PaO2 at ICU 80 ¨C 100 mmHg

Primary endpoints:
Myocardial damage (CK-MB, hs-troponine-T)

Secondary endpoints:
Hemodynamic parameters: SVRI and C.I.
microcirculation
oxidative stress
tissue/organ perfusion
clinical endpoints (duration of mechanical ventilation, length of stay, mortality).

Study objective

We hypothesize that hyperoxia during and post CABG surgery has unfavourable effects on hemodynamics, microcirculation, and ischemia/reperfusion injury, due to increased oxidative stress (ROS) affecting endothelium-derived vaso-active factors.

Study design

At baseline, immediately after operation, 6 and 12 hours after operation.

Intervention

In this study we compare different oxygen levels. We will investigate current practice (1, 2; group I) with titrated oxygen levels (group II).

group I: target PaO2 on CBP during aortic clamp time 200 ¨C 220 mmHg, PaO2 at ICU of 130-150 mm Hg
group II: : After intubation FiO2 will be decreased to 40% (provided that O2 saturation remains > 96%). Target PaO2 on CBP during aortic clamp tima 130 ¨C 150 mmHg, PaO2 at ICU 80 ¨C 100 mmHg

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Eligibility criteria

Inclusion criteria

-Age > 18 years
-Non-emergent CABG surgery
-Hb > 7.5 mmol/l
-BSA > 1.9 m2

Exclusion criteria

-Emergency surgery
-Combined cardiac surgery (heart valve combined with CABG surgery)
-Off-pump-CABG
-Presence of pre/perioperative intra-aortic balloon pump
-Medical history positive for COPD

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2013
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	30-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38987
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4230

Register	ID
NTR-old	NTR4375
CCMO	NL43882.029.13
OMON	NL-OMON38987

Study results