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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27282

Bron
NTR

Aandoening

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

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2013
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38987
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4230
NTR-old	NTR4375
CCMO	NL43882.029.13
OMON	NL-OMON38987

Resultaten