The effects of oxygen supplementation on oxidative stress biomarkers in the Emergency Department.

Published: 19-08-2019
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To investigate the effects of oxygen therapy within the first hour on the occurence of oxidative stress biomarkers at different levels of oxygenation (hypoxia, normoxia and hyperoxia).

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46013

Source
ToetsingOnline

Brief title
The short-term effects of oxygen therapy on oxidative stress.

Condition

- Other condition

Synonym
Oxidative stress, toxic effects of oxygen

Health condition

Patienten met aandoeningen waarvoor zuurstof therapue noodzakelijk is voor of bij binnenkomst op de SEH

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Mandema stipendium;overige sponsoring wordt nog aangevraagd,Kolff subsidie;Nierstichting NL.

Intervention

Keyword: Biomarkers, Emergency Department, Oxygen

Outcome measures

Primary outcome

The occurrence of oxidative stress biomarkers in patients who receive oxygen

therapy in the ED.

Secondary outcome

The association between blood oxygen saturation and the occurrence of the

different oxidative stress biomarkers.

Study description

Background summary

Much is known about the harmfull effects of hypoxia. For this reason, oxygen therapy is given to acutely ill patients easily. However, the last few years more and more is known about the detrimental effects of hyperoxia. Patients who receive too much oxygen for a longer period of time (> 24 hours) have shown to have increased comorbidities and even higher mortality rates. It is yet unknown if these detrimental effects of hyperoxia are also apparant after a short period of time (within 1 hour). Since the Emergency Departement is the designated place to start oxygen therapy, it is important to investigate if we should be cautious about the detrimental effects of a short period of hyperoxia as well.
One way to investigate the harmfull effects of oxygen is to look at the occurence of oxidative stress biomarkers in blood samples and urine. It is also yet unknown if these biomarkers occur after a short period of time.

Study objective

To investigate the effects of oxygen therapy within the first hour on the occurence of oxidative stress biomarkers at different levels of oxygenation (hypoxia, normoxia and hyperoxia).

Study design

Single center prospective cohort study.

Study burden and risks

In all included patients, an extra blood sample (9 ml) will be obtained during regular needle punction upon arrival. This will be performed trough the same needle regular blood samples are obtained, so this gives no extra discomfort. After 1 hour, a second blood sample of 9 ml will be obtained, which means 1 extra punction with a needle for the patients. Urine samples will also be collected in patients who have to urinate within the first hour after arrival, in whom a catheter will be placed or who already have a catheter. This meas that the urine sample is optional: in patients without a catheter or who do not have to urinate within the first hour, this sample will not be obtained.
Finally, patiens will receive a questionnaire 6 months after their ED visit by email.
All this make the risks for included patient very small. The most important risks are those who are part of standard drawing of blood (for example pa/discomfort or hematoma).

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

- Non-trauma patients presenting to the ED who already receive oxygen therapy started by EMS or in whom oxygen therapy is started in the ED.
- Adult (i.e. age > 18 years)
- Able to provide (deferred) informed consent themselves or informed consent can be obtained via next of kin or legal guardian

Exclusion criteria

- Hypoxia (sat <94% or PaO2 < 10 kPa) despite oxygen suppletion
- Patients who receive oxygen therapy started by EMS > 30 minutes
- Patients with an acute coronary syndrome (ACS)
- Patients with Chronic Obstructive Pulmonary Syndrome (COPD) Gold III or IV
- Patient who were in cardiac arrest pre-hospital or who go into cardiac arrest in the first hour after arrival to the ED

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	19-08-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL66915.099.18