Oxidation-reduction potential in relation to vitamin C status in criticall ill patients

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To investigate and validate the relation between vitamin C levels and severity of oxidative stress, represented by sORP and AOC levels at different laboratory processing conditions. Furthermore, to determine the relation between sORP, AOC, vitamin C...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48570

Source
ToetsingOnline

Brief title
VitC-ORP

Condition

- Other condition

Synonym
Oxidative stress, vitamin C status

Health condition

ernstig zieke patienten opgenomen op de intensive care volwassenen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Zon-MW

Intervention

Keyword: Critical illness, Intensive Care, Oxidation-reduction potential, Vitamin C

Outcome measures

Primary outcome

Plasma vitamin C concentration (µmol/l), oxidative stress parameter sORP and

the anti-oxidant capacity (AOC)

Secondary outcome

Course of vitamin C concentration during the first days of ICU treatment.

Relation between plasma vitamin C concentration and

- Severity of illness and organ failure scores:

o Acute Physiology and Chronic Health Evaluation, APACHE III and IV

scores

o Sequential organ failure assessment (SOFA) score

- Clinical outcome measures.

Study description

Background summary

Intravenous vitamin C may improve the outcome of critically ill patients by

attacking the overwhelming oxidative stress which contributes to organ damage. Critically illness-induced oxidative stress decreases plasma vitamin C levels due to increased metabolic consumption in combination with reduced recycling of dehydroascorbic acid (oxidized vitamin C) while intake is reduced. Acute deficiency is the result.Up to now, there is no fast, reliable test to quantify either oxidative stress or measure vitamin C levels. Oxidative stress is mainly assessed by indirect biochemical parameters, utilizing assays assessing damage to lipids, proteins and DNA.Their measurement is difficult, time-consuming and unfeasible in clinical practice.Similarly, proper determination of vitamin C levels requires an HPLC setting and is complex, laborious, costly and not available for daily practice. Recently, a novel technology has been developed, allowing point-of-care measurement of the oxidation-reduction potential (ORP) and anti-oxidant capacity. ORP (also called the redox potential) is the net balance in activity between oxidants and reductants. ORP could be a useful tool in clinical practice as well to estimate the degree of oxidative stress. We performed a pilot study to determine whether sORP and AOC could be useful to estimate vitamin C status in critically ill patients. High sORP and low AOC showed a good correlation with low vitamin C plasma levels.

Therefore, our hypothesis is that low vitamin C levels are related to severity of oxidative stress, represented by high sORP and low AOC levels. As a result, measurement of sORP and AOC could potentially identify critically ill patients who are vitamin C deficient and are most likely to benefit from i.v. vitamin C administration. This will be investigated in a multicenter randomised controlled trial comparing 3 grams and 10 grams vitamin C with placebo. However, it is important to investigate the different correlations between vitamin C plasma levels, ORP and AOC at different laboratory processing conditions in this validation study first (see page 13 and 14 of the protocol). After this validation study, the most reliable way of processing the samples can be chosen for implementation during the mentioned RCT which will enhance its results. Furthermore, the validation of the RedoxSYS system will contribute to its value as point-of-care measurement.

Study objective

To investigate and validate the relation between vitamin C levels and severity of oxidative stress, represented by sORP and AOC levels at different laboratory processing conditions. Furthermore, to determine the relation between sORP, AOC, vitamin C plasma concentrations and clinical outcome measures.

Study design

Single center, prospective, observational study

Study burden and risks

The study is a validation of a new point-of-care device and offers no risk for the patient. The blood will be sampled from an arterial line, which is routinely present in critically ill patient for monitoring blood pressure and blood sampling. A puncture is not necessary and the patient will not even notice the blood sampling. Clinical characteristics and outcomes of the study are variables which are routinely registered in the patient data management system of the unit. The included patients will not benefit from the study. There may however be benefit for future patients. We will include patients in which oxidative stress plays a major role (e.g. sepsis, trauma or ischemia/reperfusion injury) and thus are most likely to have vitamin C deficiency and benefit from high-dose intravenous (i.v.) vitamin C. A baseline value (at day 1) is highly important and contributes to the decision making regarding the timing of vitamin C administration. In addition, we will perform measurements at day 3 as well because a previous study showed that vitamin C concentrations decreased during the first 3 days of ICU-admission.

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

In order to be eligible to participate in this study, all of the following criteria must be met:
- * 18 years old;
- Critically ill patients admitted to the ICU (SIRS/sepsis, trauma, post cardiac arrest);
- Written informed (proxy) consent.

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2018
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	14-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66863.029.18