Intra cellular oxygen measurement during photodynamic therapy

Published: 22-06-2015
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Measure intracellular oxygen availability in humans during photodynamic therapy

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cornification and dystrophic skin disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41860

Source
ToetsingOnline

Brief title
PO2DT

Condition

- Cornification and dystrophic skin disorders

Synonym
Actinic keratosis, basal cell carcinoma, skin cancer, solar keratosis

Research involving
Human

Sponsors and support

Primary sponsor: Experimentele Anesthesiologie
Source(s) of monetary or material Support: Ministerie van OC&W,Photonics Healthcare BV

Intervention

Keyword: Oxygen, Photodynamic therapy

Outcome measures

Primary outcome

Intracellular oxygen availability

Secondary outcome

• Skin temperature at the lesion

• Sensor temperature

• Accuracy of cellular oxygen measurement (variation of repeated measurements with

stable circumstances)

• Minimum measured value, expected during local pressure on skin (expected to be less than 10 mmHg)

• Maximum measured value, expected briefly after release of the pressure. In subjects

with dense vascularization this is expected to rise to a value that is only

slightly below the arterial oxygen tension (known to be about 100mmHg in

healthy adults). Because of the measurement principle (mitoPO2 ~ 1/lifetime)

larger variations are expected at higher oxygen tensions.

• Oxygen consumption

• PDT area size

• Pain

• Body weight

• Body length

• Body mass index

• Smoking, drug, alcohol

• Parameters influencing the microcirculation such as: Medication, vessel

diseases, ..

• Clinical efficacy of PDT treatment

• Skin type

Study description

Background summary

Photodynamic therapy (PDT) is used due to its minimally invasive character for treatment of early stages of local, and superficial cancers in areas of the body accessible for light application. Other applications for PDT are for example actinic keratosis in dermatology, and macular degeneration in ophthalmology. (Piffaretti et al., 2012)

The induced cell death by PDT relies on the presence of a photosensitizer located in the target area, molecular oxygen and administration of light absorbed by a photosensitizer. One of these photosensitizers is protoporphyrin IX (PpIX), an endogenous mitochondrially produced photoactive molecule. (Poulson, 1976; Treffry & Ainsworth, 1974). Photo-activated PpIX transforms the triplet-ground state oxygen into singlet oxygen molecules. Singlet reactive oxygen molecules are one of the main working mechanisms of PDT damaging the mitochondria and internal cell organelles. (Allison & Moghissi, 2013, Buytaert, Dewaele, & Agostinis, 2007, Morgan & Oseroff, 2001). Photodynamic therapy therefore depends on the availability of oxygen in the cells of the target tissue. It has so far not been possible to measure such cellular oxygen availability.

Despite encouraging results with PDT some clinicians avoid using this therapy due to observed fluctuations in intra- and inter-patient therapeutic outcomes. (Radakovic-Fijan, Blecha-Thalhammer, Kittler, Hönigsmann, & Tanew, 2005) These fluctuations generally are associated with the intra cellular oxygen level and the uneven distributed photosensitizer. These uncertainties can be countered by monitoring in real time available intracellular oxygen adjusting the light dosimetry as ultimate result. (Busch, 2006; Glanzmann & Hadjur, 1998)

The possibility of measuring intra cellular oxygen during PDT may help improve understanding of the mechanisms involved in the oxygenation and photosensitization of biological tissues. (Piffaretti, 2011; Piffaretti et al.,

2012) It is likely that with this new information the efficacy and efficiency of PDT for a specific patient can be indicated.

Study objective

Measure intracellular oxygen availability in humans during photodynamic therapy

Study design

Observational study

Study burden and risks

No extra riks are expected as result of the oxygen availability measurement. In the volunteer study done in the Erasmus MC NL 37911.078.11.v06 / MEC-2001-397 only PDT effect were seen as adverse event (AE). No photodynamic effects are reported with this device. These AEs were a result of careless behaviour exposing the light sensitive area to sunlight. These effects are already expected in PDT so no extra risks are identified. The extra burden for the patient is small because the standard protocol is done with a few extra measurements taking in total 150 min in which 120 min waiting time is included between the therapy PDT sessions.

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

Undergo 5-aminolevulinic acid precursor photodynamic therapy

Exclusion criteria

Less than 18 years of age

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):	13-07-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	22-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51187.078.14