Optimising Photodynamic Therapy for the Treatment of Head and Neck Cancer

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The main objective of the study is to monitor the factors effecting success of PDT, namely oxygen, photosensitizer concentration and, light dose before and during illumination to gather data that can be clinically correlated and later implemented.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON34093

Source
ToetsingOnline

Brief title
Optimising PDT

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Head and neck therapeutic procedures

Synonym
head and neck cancers

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: head and neck cancer, Photodynamic therapy, spectrometry

Outcome measures

Primary outcome

Study parameters:Spectrosopic quantitative analysis of oxygen saturation and

mTHPC concentration in tumor tissue, light dosimetry, serum MTHPC

concentration.

Secondary outcome

none

Study description

Background summary

mTHPC mediated Photodynamic therapy (PDT) is an EMEA approved therapy for palliative treatment of head and neck cancers . While superficial tumors are treated with surface illumination deeper tumors can be treated with interstitial PDT . There is a variation of clinical response with some tumors not fully responding . The response to PDT depends on the presence of three components; light, photosensitizer and oxygen . If any one is missing, there is no biological effect. Studies have shown that inter-and intra-subject differences in parameters such as tissue optical properties, uptake/synthesis of photosensitizer and tissue response to PDT can lead to wide variations in the light dose delivered during PDT . In pre-clinical models, we and others have shown that monitoring of PDT is possible non-invasively by using fluorescence and reflectance spectroscopy, in combination with state of the art light dosimetry. While very important advances have been made in these models, it is now necessary to translate these approaches to the clinic where the relationship between treatment parameters and delivered PDT dose can be significantly different.

Study objective

The main objective of the study is to monitor the factors effecting success of PDT, namely oxygen, photosensitizer concentration and, light dose before and during illumination to gather data that can be clinically correlated and later

implemented.

Study design

The proposed study is an observational study which wil be conducted on the patients taking part in PDT arm of the study: *A multi-centre cost-effectiveness evaluation of a novel treatment option in the Netherlands: Photo Dynamic Therapy with temoporfin for the treatment of advanced incurable head and neck cancers, for whom prior conventional treatments have failed. Short title: Cost-effectiveness of temoporfin-PDT*; PTC09.1229/M09PDT. The oxygen saturation and photosensitizer concentration of the tumor tissue will be measured by using non-invasive spectroscopic techniques, each day between injection of MTHPC and illumination (4 days) and before and after illumination. Light dosimetry will be conducted during illumination. The collected data will be correlated with clinical results of the aforementioned study.

Study burden and risks

There are no medical risks associated with the study. The patients will have to come to the hospital three extra days for non-invasive measurements. The travel costs will be reimbursed.

Contacts

Public
Het Nederland Kanker Instituut, Antoni van Leeuwenhoek

121 Plesmanlaan
1066CX Amsterdam
NL
Scientific
Het Nederland Kanker Instituut, Antoni van Leeuwenhoek

121 Plesmanlaan
1066CX Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients included in the PDT arm of the study : *a multi-centre cost-effectiveness evaluation of a novel treatment option in the Netherlands: photo dynamic therapy with temoporfin for the treatment of advanced incurable head and neck cancers, for whom prior conventional treatments have failed* (PTC09.1229/M09PDT).

Exclusion criteria

not applicable

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32343.031.10