Optical spectroscopy as a novel tool in the diagnostics of skin neoplasms.

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Primary Objective: To quantify the tissue light scattering, absorbing and fluorescence properties of different stages of skin (pre)cancer using multi-diameter single fiber reflectance (MDSFR) spectroscopy. Secondary Objective(s): To correlate the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38657

Source
ToetsingOnline

Brief title
Optical diagnosis of skin neoplasms.

Condition

- Skin neoplasms malignant and unspecified

Synonym
Skin cancer, skin neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: vanuit kostenplaats (9040) behorende bij medische specialist alhier (prof. dr. T.E.C. Nijsten)

Intervention

Keyword: Diagnostics, Multi-diameter single fiber reflectance, Skin malignancies, Spectroscopy

Outcome measures

Primary outcome

Parameters that will be measured are: blood oxygen saturation, blood volume fraction, vessel diameter, melanin, beta-carotene and bilirubin concentration, autofluorescence and reduced scattering coefficient. Every parameter will be investigated for its difference between lesions and capability to predict the nature of the lesion. As a control, sun exposed or normal skin of the same subject is measured as well.

Secondary outcome

Nanostructural changes of the skin will be evaluated in 15 biopsies (5 per lesion type) using electron microscopy. Biopsy will be performed on the same site as the measurement. Electron microscopy of these biopsies will be related to the spectroscopic data.

Study description

Background summary

Skin cancer is the most common type of cancer in The Netherlands. Research by the Integrated Cancer Center Netherlands showed that in 2011 over 11.000 new cases of skin cancer were reported. This figure is excluding the most common type of skin cancer, basocellular carcinoma. Although not centrally registered, it is estimated that this type is newly diagnosed over 20.000 times each year.

The diagnosis of skin cancer consists of several steps. First, the physician will make a list of differential diagnoses based on clinical findings. Subsequently, a biopsy is performed, which is sent to the pathologist for

histological examination. The treatment is based on the outcome of this histological examination. The process of pathologic examination takes time and money. Furthermore, subtle changes in the nanostructure of the tissue, early indicators of disease, are missed in conventional, routine histology.

To expand the diagnostic process, this research proposal will investigate the value of multi-diameter single fiber reflectance (MDSFR) spectroscopy. MDSFR is a new quantitative diagnostic tool based on the light scattering, absorption and fluorescence properties of tissue. It consists of a multiple fibers embedded in a single probe with a light emitting and collecting part. Light that is directed at the skin will be scattered in other directions by (sub)cellular structures. Additionally, part of the light will be absorbed by melanin in melanocytes and hemoglobin in erythrocytes. Furthermore, some absorbing molecules (e.g. NADH, FAD, collagen, keratin) re-emit light at a higher wavelength (fluorescence). Differences in the light scattering, absorption and autofluorescence properties between normal and suspicious skin can be measured with this new method. These changes may be related to cancer. In a similar way, in other fields of research, lung cancer, diabetes mellitus type and monitoring during photodynamic therapy (PDT) and outcome of PDT were investigated.

MDSFR has been studied extensively in skin-mimicking phantoms. With the use of mathematical models, behavior of light in this skin-like environment was examined. Absorption, scattering and fluorescence could be readily measured. Changes in the ultrastructure of the skin occur early in the development of cancer. It is hypothesized that these changes are due to disturbances in the cytoskeleton. We hypothesize that MDSFR spectroscopy will be sensitive to these early changes and thus pick up cancer earlier in its development.

Study objective

Primary Objective: To quantify the tissue light scattering, absorbing and fluorescence properties of different stages of skin (pre)cancer using multi-diameter single fiber reflectance (MDSFR) spectroscopy.

Secondary Objective(s): To correlate the measured light scattering properties to the underlying nanoscale structural changes within the tissue by performing electron microscopy on biopsies taken at the same location as the optical measurements.

Study design

The design of the experiment will be an observational non-randomized cohort study of which the majority of subjects will only undergo non-invasive (optical) measurements. A small subset will also undergo a biopsy.

If conventional pathology concludes a different diagnosis as the clinical diagnosis, the subject will be placed in the appropriate study arm or excluded. Lesions that do not fit in any arm after conventional pathology will be discarded.

Study burden and risks

No serious adverse side effects are expected from MDSFR measurements. The intensity of the light (from a halogen light source) used in the measurements is less than 200 microwatts, which is far beneath the threshold for thermal damage of tissue; the patients tissue as well as the eyes of the bystanders are not at risk. Other damage mechanisms at these wavelengths (>400 nm) are not known. The intensity of the light from an LED (365 nm) to induce fluorescence is less than 100 microwatts, which is an order of magnitude below the exposure limit.

After biopsy, there is a small chance of hemorrhage or infection. Both risks are low.

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

* Age 18 or over
* Clinically suspect lesion; either actinic keratosis, squamous cell carcinoma or basal cell carcinoma
* No prior treatment for the lesion
* Good understanding of Dutch or English;Additional inclusion criterion for biopsy
* Lesion size * 2 cm

Exclusion criteria

* Prior treatment of the lesion
* Serious other illness

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	105

Type:	Anticipated

Ethics review

Approved WMO Date:	08-01-2014
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	NL45228.078.13