In vivo assessment of pigmented skin lesions by Raman spectroscopy

Published: 13-03-2017
Last updated: 11-04-2024

Primary Objective: to explore the feasibility and to identify potential hurdles of in vivo assessment of pigmented skin lesions by Raman spectroscopy.Secondary Objective(s): - to compare in vivo measurements with the results obtained by ex vivo...

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

Summary

ID

NL-OMON43252

Source
ToetsingOnline

Brief title
RASKIN in vivo study

Condition

- Skin neoplasms malignant and unspecified
- Skin neoplasms malignant and unspecified

Synonym
Melanoma, mole., skin cancer of pigment-containing cells. Nevus

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Agentschap NL (IOP Photonic Devices)

Intervention

Keyword: Diagnostic, Melanoma, Pigmented skin lesion, Raman spectroscopy

Outcome measures

Primary outcome

Clinical and when available the pathological diagnosis of the pigmented skin lesion (melanoma or benign skin lesion) will be correlated with the measured Raman spectra of the lesions.

Secondary outcome

Age of the patient, location and aspect of the lesion, clinical differential diagnosis.

Study description

Background summary

Melanoma is the most lethal form of skin cancer. Worldwide 200.000 patients are diagnosed with melanoma each year and the incidence is increasing. Clinical diagnosis of melanoma at an early stage is difficult even for the experienced dermatologist. Assessments are generally based on visual inspection, with or without tools such as dermoscopy. An objective, low-cost, easy-to-use tool is needed to assist dermatologists and primary care physicians in making assessments of pigmented skin lesions.The RASKIN project has started 2012 with the ultimate goal to develop a low-cost, easy-to-use Raman-spectroscopic device for use by dermatologists and primary care physicians, for objective, rapid identification of pigmented skin lesions suspicious of melanoma. In this project we have developed a pre-clinical device and used it to record an extensive data set of over 300 pigmented skin lesions suspected of melanoma and surgically excised for histopathological examination (ex vivo) at LUMC. This ex vivo work has demonstrated that Raman spectroscopy has the potential to provide an objective clinical tool to improve the clinical diagnostic accuracy of pigmented skin lesions suspected of melanoma. The next necessary step is to investigate the feasibility to perform the Raman measurements in vivo, directly on the pigmenbted skin lesion, using a fiber-optic probe connected to the Raman device.

Study objective

Primary Objective: to explore the feasibility and to identify potential hurdles of in vivo assessment of pigmented skin lesions by Raman spectroscopy.

Secondary Objective(s):
- to compare in vivo measurements with the results obtained by ex vivo measurements on excised skin lesions suspicious of melanoma.
- to compare Raman spectra of suspicious lesions with benign lesions from the same patient for reference.
- to validate the measurement protocol for in vivo assessment of suspicious lesions within a clinical workflow.

Study design

Observational study. The study aims at exploring the feasibility of in vivo application of the method, including identification of practical hurdles and collection of a preliminary set of in vivo data.

Study burden and risks

To only risk associated with this study, harm to the eyes form the laser light used for Raman measurements, is eliminated by wearing safety goggles. The measurements are painless and will take at most 25 minutes. the results of the Raman measurements do not impact on the diagnosis or treatment. In the context of the study pigmented skin lesions that are surgically removed will be examined by a second pathologist; if in rare cases the conclusion of pathological examination would differ with respect to the diagnosis of melanoma, pathological examination will be repeated at LUMC; if the conclusion would be adapted by the clinical pathologist at LUMC after revision the patient would be informed by the treating dermatologist.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300 RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2

Leiden 2300 RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult, mentally competent persons with pigmented skin lesions

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- the lesion(s) are on body locations inaccessible to the Raman measurement
- patient is physically capable of undergoing the Raman measurement (which requires the patient to not move during the measurement)
- patient is mentally not capable of participation, e.g. because of anxiety

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60124.058.16