Metastases of cutaneous squamous cell carcinoma in organ transplant recipients - The *SCOPE-ITSCC metastases study*

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

Summary

ID

NL-OMON39568

Source
ToetsingOnline

Brief title
SCOPE-ITSCC metastases study

Condition

- Skin neoplasms malignant and unspecified

Synonym
Skin cancer, squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: metastases, organ transplant recipients, skin cancer

Outcome measures

Primary outcome

The primary outcome of the study is the development of metastases of cutaneous invasive SCC within 2 years and the time period until the first metastases is discovered.

Secondary outcome

Assessment of risk factors for the design of future case-control studies.

Study description

Background summary

Skin cancer is the most common cancer in white populations. Organ transplant recipients (OTR) have a highly increased risk of cutaneous squamous cell carcinoma (SCC) and many OTR develop multiple SCC. SCC have the potential to metastasize, usually within 1 year after the initial diagnosis. The risk of metastases varies in the immunocompetent population between 0.1% and 9.9%. Immunosuppression is often mentioned as a risk factor for developing metastases, but in our clinical practice we do not often see OTR with SCC metastases. No prospective clinical studies are available to estimate the cumulative incidence of SCC metastases in OTR.

In a large international multicenter prospective observational study a total number of 1000 OTR with a histologically proven cutaneous SCC will be included in 10 centers and followed during 2 years to establish the cumulative incidence of metastases in OTR with cutaneous SCC. This study will be coordinated by the department of dermatology of the LUMC and will be performed in collaboration with SCOPE (Skin Care in Organ transplant recipients in Europe, http://www.scopenetwork.org/) and ITSCC (International Transplant Skin Cancer Collaborative, http://www.itscc.org/).

Study objective

The objective of this multicenter prospective observational study is to

estimate in a follow-up period of 2 years the cumulative incidence of metastases in OTR with cutaneous invasive SCC. In addition we will estimate the contribution of risk factors for metastases in these patients such as tumor localization, size, depth and grade, perineural tumor invasion and other potential risk factors to facilitate the design of a future case control study to asses the importance of these risk factors for the development of SCC metastases in OTR.

Study design

OTR with skin carcinomas are regularly seen in the outpatient dermatological clinic of the LUMC and other Dutch and foreign specialized out-patient dermatological OTR clinics. When a patient develops a first or a new SCC, the patient will be asked to participate in the study. The patient will be asked to fill in a questionnaire together with the investigator. Patient, tumor, follow-up data and treatment characteristics will be registered by the investigator and data about diagnostic procedures will be recorded. Standard medical care will be given to all patients.

Study burden and risks

Except for filling in the questionnaire with the help of the investigator, which will require 5 minutes of time per lesion, there will be no burden for the patient. There will be no risk in addition to the standard medical care. All data will be entered in an ACCESS database anonymously. The non-anonymous printed questionnaire will be kept as a record for the local treating physician, and will not be used for the data analyses.

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

Organ-transplant recipients (OTR).
Histologically proven cutaneous invasive SCC at time of inclusion.

Exclusion criteria

Lack of consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2013
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	11-07-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2014
Application type:	Amendment
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	NL40957.058.12