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

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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...

**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

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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**

#### **Public**

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#### Scientific

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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