Pain as diagnostic marker for cutaneous squamous cell carcinoma.

Published: 27-07-2009
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The aim of this study is to study whether the symptom pain is a diagnostic marker for a cutaneous squamous cell carcinoma.

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

Summary

ID

NL-OMON33043

Source
ToetsingOnline

Brief title
Pain-study SCOPE

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: organ-transplant recipients, pain, squamous cell carcinoma

Outcome measures

Primary outcome

Pain as a diagnostic marker for cutaneous squamous cell carcinoma

Secondary outcome

Studying the relation between pain and penetration depth (histology) of

squamous cell carcinoma.

Studying the relation between pain and perineural invasion (histology) of

squamous cell carcinoma.

Study description

Background summary

Organ transplant recipients have an increased risk to develop warts and skin malignancies. Due to the multiplicity of the tumors (several hundreds) it could be very difficult to distinguish benign, premalign and malign skin lesions. Under dermatologist it is presumed that pain is clinical symptom of squamous cell carcinoma, although this has never been confirmed by scientific research.

Study objective

The aim of this study is to study whether the symptom pain is a diagnostic marker for a cutaneous squamous cell carcinoma.

Study design

For every biopsied lesion in organ transplant recipients a questionnaire about pain will be filled in.
The time to fill in the questionnaire will take approximately 3-5 minutes.

Study burden and risks

The care during our specialized clinic for organ transplant recipients will be continued exactly the same way as before the start of the study. When lesions should be biopsied we will ask some additional questions about pain with the

help of the questionnaire.

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

1)Only organ-transplant recipients (OTR).
2)All excised skin or biopsied skin lesions (medical reason, cosmetic reason etc.).
3)From one patient more than one tumor can be taken per visit and assessments on later visits are possible. ALL biopsies should be included!! For each biopsy a new ACCESS form has to be filled in.

Exclusion criteria

lack of consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	27-07-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL28380.058.09