DNA methylation profiling in blood of patients with cutaneous squamous cell carcinoma (cSCC) after organ transplantation

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The main objective of this study is to identify changes in DNA methylation of CD3+ T cells associated with cSCC after organ transplantation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42690

Source
ToetsingOnline

Brief title
Methylation profiling in post-transplant cSCC

Condition

- Other condition
- Skin neoplasms malignant and unspecified

Synonym
post-transplant cutaneous squamous cell carcinoma, post-transplant skin cancer

Health condition

orgaantransplantatie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: cutaneous squamous cell carcinoma, DNA methylation, immunity, organ transplantation

Outcome measures

Primary outcome

The primary study parameter is the difference in DNA methylation in CD3+ T

cells between organ transplant recipients who developed cSCC and organ

recipients who did not develop a malignancy.

Secondary outcome

not applicable

Study description

Background summary

The most common malignancy after solid organ transplantation is cutaneous squamous cell carcinoma (cSCC). Compared to the general population this recurrent skin tumour is 200 times more common in transplant recipients and grows and metastasizes more rapidly leading to increased morbidity and mortality. The chronic use of non-specific immunosuppressive medication after transplantation suppresses T cell functions, including T cell reactivity against donor antigen, but also disrupts antiviral and antitumour immunosurveillance by T cells. Aberrant DNA methylation profiles are more and more associated with diseases, specifically with the development and progression of malignancies. Here we hypothesize that the DNA methylation profile of CD3+ T cells in blood is significantly different in organ transplant recipients who developed a cSCC compared to organ transplant recipients who did not develop a malignancy.

Study objective

The main objective of this study is to identify changes in DNA methylation of CD3+ T cells associated with cSCC after organ transplantation.

Study design

This is an investigator-driven, observational (case-control) study comparing DNA methylation profiles of CD3+ T cells from organ transplant recipients with and without cSCC.

Study burden and risks

During routinely follow-up of transplant recipients blood is drawn to measure trough levels of the immunosuppressive medication and at the same moment blood will be drawn for this study (5 heparin tubes of 6 ml and 1 coaggulation tube of 6 ml = 36ml blood). There are no risks involved in participation of the study. The included patients do not directly benefit from participation, though they could contribute to identification of patients at risk for the development of a post-transplant cSCC in the future.

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

Patients with (cases) compared to patients without (controls) cutaneous squamous cel carcinoma after their first organ transplantation

Exclusion criteria

Previous transplantation (either solid or non-solid organ transplantation)
History and presence of other malignancies (including skin malignancies before transplantation)
Under 18 years of age

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2015
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	NL54386.078.15