Quality of life of patients with actinic keratoses and/or a superficial basal cell carcinoma treated with 5% Imiquimod cream.

Published: 28-01-2009
Last updated: 06-05-2024

To evaluate patient related outcomes mainly quality of life and treatment satisfaction. Side effects and therapy adherence were also evaluated because these can interfere with quality of life and treatment satisfaction.

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

Summary

ID

NL-OMON33695

Source
ToetsingOnline

Brief title
QOL of patients treated with Imiquimod.

Condition

- Skin neoplasms malignant and unspecified

Synonym
actinic keratoses/solar keratoses and superficial basal cell carcinoma/basal cell cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: MedaPharma

Intervention

Keyword: actinic keratoses, basal cell carcinoma, Imiquimod, Quality of life

Outcome measures

Primary outcome

The proportion of patients of which HRQOL (quality of life) increases after treatment, the proportion of patients satisfied with the treatment and the proportion of patients with therapy adherence >=80% will be described. HRQOL scores before and after treatment will be compared by the Mann-Whitney test.

Regressioncoefficients (confidence incidence)will describe which demografic and diseasecharacteristics are related to a change in HRQOL. With multivariable logistic regression we will analyze what variables are markers for (good) therapy adherence and treatment satisfaction (Adjusted odds ratios and confidence interval).

Secondary outcome

not applicable

Study description

Background summary

Immunomodulating therapy for the treatment of actinic keratoses and superficial basal cell carcinoma is a relatively new treatment. Several studies show that Imiquimod is an effective treatment for the above mentioned indications. Less is known about how the patient experiences this topical treatment which they can apply at home.

Study objective

To evaluate patient related outcomes mainly quality of life and treatment satisfaction. Side effects and therapy adherence were also evaluated because these can interfere with quality of life and treatment satisfaction.

Study design

This is an open clinical study

Study burden and risks

Patients will visit the outpatient clinic twice. Patients are asked to fill out questionnaires at three different moments (before-directly after treatment and when patients visit the outcome clinic for regular planned follow-up)and a diary (patients are asked to fill this out during treatment).

Contacts

Public
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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 actinic keratoses and/or a superficial basalcellcarcinoma, PA not neseccary
Patients are capable of treating themselve or know a person who can assist them
Patients older than 18 years
Signed informed consent

Exclusion criteria

patients mentally or physically not capable of filling out the questionnaires/diary
Patienst who are not able to understand Dutch in a way they need to to fill out the questionnaires/diary

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-06-2009
Enrollment:	500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aldara 5% cream

Generic name:	Imiquimod 5% cream
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-01-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-02-2009
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
EudraCT	EUCTR2008-002501-39-NL
CCMO	NL23594.078.08