Validation of the questionnaire Skindex-17

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The goal of this study is to validate and interpret a new HRQOL instrument and to analyse commonly used outcome measurements (PGA, PtGA) in dermatology.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30768

Source
ToetsingOnline

Brief title
The quality-trial

Condition

- Other condition
- Epidermal and dermal conditions

Synonym
quality of life

Health condition

algemeen welzijn

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: dermatology, quality of life, questionnaire

Outcome measures

Primary outcome

1. Validation and research of characteristics of the Skindex-17

2. Research of discrepantion between PtGA and PGA. Research of predictive values

3. Research of PtGA, PGA and Health Related Quality of Life (HRQoL)

4. Comparison of psychometric characteristics of the SF-36, EQOL-5D

5. Creation of a Quality-Life Adjusted (QALY)-list of skindiseases using SF-36

and EQOL-5D.

Transforming Skindex-17 scores into QALY*s .

Secondary outcome

not applicable

Study description

Background summary

Skin diseases have a significant impact on the health-related quality of life (HRQOL) of patients. It is believed that the impact of inflammatory skindiseases such as psoriasis and atopic dermatitis are comparible to the effect of other chronic diseases such as diabetes, reumatic artritis, hypertension and Crohn*s disease. To measure the impact of diseases on the quality of life, several instruments are available and these can be grouped in generic instruments (eg. SF-36), dermatology-specific instruments (eg. Skindex-29 and Dermatology Life Quality Index: DLQI) or disease-specific questionnaires (eg. Psoriasis Disability Index). The majority of the

dermatology-specific instruments have been developed in the early 90*s, of which the Skindex-29 among the most commonly used and widely accepted tools. Recently we have reduced the Skindex-29 using item response theory models in the Skindex-17. The later is fitted both the classical test theory and item response theory model well in a population of Italian dermatology patients. However, before new instruments are accepted, they should be validated extensively in populations that vary culturally, demographically and in diseases severity.

Little is known what drives patients to score HRQOL items or global assessments. Although it has not been studied previously, it is likely that several demographic and disease related factors are important predictors of how patient rate their disease and the impact of their disease on their lives. The only varieble studied is clinical disease severity (assessed by the dermatologists) and, surprisingly, several studies show that the level of clinical disease severity is not well correlated with HRQOL impairment. Identifying these predictors may help us to better understand outcome measurements used in dermatology.
Moreover, dermatologists underestimate the impact of the disease on patients` lifes substantially. This may affect the management patients need or expect, which may result in dissatisfied patients. To maximize patinets`treatments it would be usefull to study and potential predictors of the discrepancy between patients and physicians assessments. In reumatology, it has been demonstrated that there are significant differences between the patinet and physician global assessmnets. Factors significantly associated factors with this discrepancy were eg. age, descent and education level of the patient.

Study objective

The goal of this study is to validate and interpret a new HRQOL instrument and to analyse commonly used outcome measurements (PGA, PtGA) in dermatology.

Study design

A cross sectional study of patients visiting the outpatient clinic of the Department of Dermatology. At most at three monents in time, patinets are asked to complete a questionnaire.

Study burden and risks

Time strain: Filling in questionnaires
First visit: 30 minutes
48 h after first visit (just new patients): 5 minutes
First control visit: 5 minutes

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 older than 18 years of age.
- Visit outpatient clinic of Dermatology Erasmus MC
- Sufficient knowledge of the Dutch language
- Capable of filling in a questionnaire
- Informed Consent

Exclusion criteria

-no dermatological diagnosis

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):	01-04-2008
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	10-03-2010
Application type:	Amendment
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	NL15515.078.07