Health-Related Quality of Life Assessment And Communication During 48 Weeks of Treatment of Moderate to Severe Psoriasis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24504

Source
Nationaal Trial Register

Brief title
Q-ACT

Health condition

Keywords:
Psoriasis, Health-Related Quality of Life, Etanercept.
doctor-patient communication, psoriasis patients

Sponsors and support

Primary sponsor: Stichting Aquamarijn
Meibergdreef 9
1105 AZ AMSTERDAM ZO
Source(s) of monetary or material Support: Pfizer BV

Intervention

Outcome measures

Primary outcome

Primary Efficacy Endpoints:

1. Communication (COM):

Communication Questionnaire (COM), a study-specific two-dimensional questionnaire concerning

a) the quantity of HRQL-communication during consultations

b) the satisfaction with doctor ¨C patient communication.

2. Overall HRQL:

Dermatology Life Quality Index, a well-established dermatology-specific HRQL measure (DLQI).

Secondary outcome

Secondary Efficacy Endpoints:

1. Health Status (HS)

Medical Outcomes Study 36-item Short-Form General Health Survey, a well-established, eight-dimensional, generic health status measure (SF-36).

2. Global Disease Severity (GDS)

a. Psoriasis Area and Severity Index (PASI)

b. Physician Global Assessment & Patient Global Assessment.

3. Overall Evaluation (OE)

A study-specific questionnaire concerning

a) satisfaction with the treatment process, including doctor ¨C patient communication

b) satisfaction with treatment outcomes

c) the feasibility of HRQL-assessment and HRQL- communication in dermatological practice at large.

Study description

Background summary

Title:

Health-Related Quality of Life (HRQL) Assessment And Communication During 48 Weeks Of Treatment Of Psoriasis Patients With Etanercept

Background:

There is a growing interest in the application of HRQL assessment in clinical practice. This assessment is considered to be an aid for monitoring the therapeutic process, the communication with the patient, and for improving treatment outcome.

Objectives:

1. To assess the efficacy of HRQL-assessment and HRQL-communication in dermatological practice during 48-weeks of treatment of psoriasis patients with etanercept.

2. To examine the course of HRQL during 48-weeks of treatment with etanercept, and to assess the degree of improvement of HRQL.

Study Design:

A multi-centre, open label, phase IV, cluster randomized controlled trial. Study centres will be randomly allocated to the intervention or control group.

Subject Population to be included:

Approximately 200 patients with moderate to severe psoriasis (PASI > 8). Patients will be included in the trial after etanercept has been prescribed by the dermatologist.

Primary and secondary endpoints:

Communication Questionnaire, Dermatology Life Quality Index, SF-36, PASI and a global assessment of disease severity.

Intervention:

Standardized HRQL-assessment and HRQL-communication in dermatological practice. Prior to each consultation HRQL will be assessed on desk-top pc at the treatment center. During each consultation, HRQL-answers, HRQL-scores, coping behaviour and disease management will be discussed. Prior to the start of the study dermatologists in the intervention group will be educated and trained in standardized HRQL-assessment and HRQL-communication.

Study duration:

The inclusion period will take 72 to 96 weeks. The duration of patient participation will be 48 weeks. ¡°First patient in¡± to be expected: Final Quarter of 2008.

Study objective

It is hypothesized that the application of a HRQoL intervention in dermatology practice will have a positive impact on patients´ health-related quality of life as well as on doctor-patient communication.

Study design

Measurements will take place at baseline, week 6, 12, 24, 36, and 48.

Intervention

Standardized HRQL-assessment and HRQL-communication in dermatological practice. Prior to each consultation HRQL will be assessed on desk-top pc at the treatment centre. During each consultation, HRQL-answers, HRQL-scores, coping behaviour and disease management will be discussed.

Included patients receive either

1) treatment with etanercept and standardized HRQL-assessment and HRQL-communication (intervention group) or
2) treatment with etanercept (control group).

Contacts

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Eligibility criteria

Inclusion criteria

1. Eighteen years of age or older at time of consent.

2. Established diagnosis of plaque psoriasis.

3. Meeting the Dutch reimbursement criteria for etanercept:

■ PASI > 10, or PASI > 8 with Skindex-29 score > 35.

■ Ineffective or contra-indications to PUVA treatment twice weekly for 10 weeks.

■ Ineffective or contra-indications to treatment with cyclosporine 3-5 mg/kg/day for 16 weeks.

■ Ineffective or contra-indications to treatment with MTX 22,5 mg/day for 16 weeks.

4. Naive to treatment with etanercept.

Exclusion criteria

1. Patients of childbearing potential who are not using or willing to use adequate anti-conceptive measures.

2. Contraindications for the use of etanercept: sepsis or risk of sepsis, including local infections.

3. Previous anti-TNF treatment.

4 .Patients who are mentally and/or physically not able to complete the study questionnaire(s).

5. Patients who insufficiently speak the Dutch language to fully understand and complete the study questionnaire(s).

6. Patients who are not willing or not able to discuss HRQL-issues.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008

Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion Date:	01-07-2008
Application type:	First submission

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
NTR-new	NL1315
NTR-old	NTR1364
Other	Stichting Aquamarijn : 0881A1-4516
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A