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

Gepubliceerd: 01-07-2008 Laatst bijgewerkt: 18-08-2022

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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24504

**Bron**
Nationaal Trial Register

**Verkorte titel**
Q-ACT

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Stichting Aquamarijn
Meibergdreef 9
1105 AZ AMSTERDAM ZO
**Overige ondersteuning:** Pfizer BV

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Primary Efficacy Endpoints: <br><br>

1. Communication (COM):<br>
Communication Questionnaire (COM), a study-specific two-dimensional questionnaire concerning<br>
a) the quantity of HRQL-communication during consultations<br>
b) the satisfaction with doctor ¨C patient communication.
<br><br>
2. Overall HRQL:<br>
Dermatology Life Quality Index, a well-established dermatology-specific HRQL measure (DLQI).

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

**Doel van het onderzoek**

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.

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

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).

# Contactpersonen

## Publiek

Postbus 22660
C.A.C. Prinsen
Academisch Medisch Centrum - UvA
Poli Huidziekten - kamer A0.224

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662757

## Wetenschappelijk

Postbus 22660
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Amsterdam 1100 DD
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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-10-2008 |
| Aantal proefpersonen: | 200 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-07-2008 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1315 |
| NTR-old | NTR1364 |
| Ander register | Stichting Aquamarijn : 0881A1-4516 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A