"PSOGEN:Effect adalimumab op zelfbeeld en seksueel functioneren bij matige en ernstige psoriasis van de anogenitale regio; prospectief, open label pilot onderzoek"

Published: 29-04-2009
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The objective is to assess the effect of adalimumab on selfconfidence and sexuality of patients with anogenital psoriasis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON33188

Source
ToetsingOnline

Brief title
PSOGEN

Condition

- Epidermal and dermal conditions

Synonym
Psoriasis, scaling skin condition

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Abbott,Dit betreft een investigator initiated door farmaceut gesponsord onderzoek

Intervention

Keyword: Adalimumab, Anogenitaal, Psoriasis

Outcome measures

Primary outcome

Lower scores on the measuring questionnaires.

Secondary outcome

None

Study description

Background summary

Psoriasis is a chronic inflammatory disease of the skin of unknown etiology.About 2-3% of the world population is affected by it. It is accompanied by heavy psychological burden. Altough psoriasis usually manifests on knees, elbows and the head, lesions in anogenital region are frequently seen.There are indications that the experience of sexuality can be nefatively influenced by it. On assessment of severity of psoriasis this is not taken into account. It is to be expected that this problem will improve with treatment of psoriasis. Validated questionnaires exist for evaluation of sexuality, self confidence and relationships: DS-c (inventory of depressive symptomatology), SEAR (Self-Esteem and Relationship), IIEF (International Index of Erectile Dysfunction) en FSFI(Female Sexual Function Index) . They have been designed to measure the problems we are trying to assess. The PSOGEN questionnaire is designed by the study team and will show difference in how ano-genital psoriasis versus psoriasis in other body sites is experienced by the patients. Also the way in which patients grade the importance of sexuality and intimacy can be expressed by this instrument.

Study objective

The objective is to assess the effect of adalimumab on selfconfidence and

sexuality of patients with anogenital psoriasis.

Study design

This is a prospective study conducted in two hospitals in Netherlands. It is a pilot which will eventually lead to a controled double blind trial.

Study burden and risks

Filling in the questionnares and physical and psychological examination cost time.
No benefit to patients is to be expected from this study.

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

-Having psoriasis of the anogenital region
-The patient will be treated with adalimumab by attending physician

Exclusion criteria

-Younger than 18
-Homosexual
-Unwilling to participate

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Humira
Generic name:	Adalimumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	29-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2009
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	EUCTR2009-011625-13-NL
CCMO	NL26555.078.09