Dose decrease of biologics in psoriasis patients with low disease activity.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24722

Source
NTR

Health condition

psoriasis, biologics, tnf-alfa remmers, etanercept, adalimumab, ustekinumab, dosis reductie, dose reduction, dose decrease

Sponsors and support

Primary sponsor: Radboudumc, Nijmegen, The Netherlands
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Psoriasis Area and Severity Index (PASI) at 12 months

Secondary outcome

Dermatology Life Quality Index (DLQI) at 12 months

PASI scores at each time point

Time until flare

Trough level antidrug antibodies and serum drug levels at each time point

hsCRP at each time point

SAEs

Study description

Background summary

Moderate to severe psoriasis can be treated succesfully with biologics. However, we do not know what the lowest possible dose is in individual patients that have a stable low disease activity. We propose to lower the dose with tight control of disease activity (PASI score) and dermatology-related quality of life (DLQI) in order to improve safety and cost-effectivenes.

Study objective

Dosages can be lowered succesfully in patients with a stable low disease activity and quality of life. This improves safety and cost-effectiveness.

Study design

0-3-6-9-12 months

Intervention

Lowering frequency of biologic given

Contacts

Public
JMPA van den Reek
Nijmegen
The Netherlands
Scientific
JMPA van den Reek
Nijmegen
The Netherlands

Eligibility criteria

Inclusion criteria

(1) Treatment of at least 6 months with one biologic

(2) During the last 6 months, subsequent low disease activity scores (PASI (psoriasis area and severity index) <5) until the moment of inclusion. At least 2 PASI scores should be available.

(3) Good disease-related quality of life (DLQI (dermatology life quality index) ≤5) at the moment of inclusion in the study

• Established diagnosis of plaque psoriasis.

• Receiving treatment with adalimumab, etanercept, or ustekinumab.

• Age ≥18 years.

Exclusion criteria

• Psoriasis itself is not the main reason for biologic prescription (e.g. when a patient has RA and psoriasis, and RA is the main reason for the biologic).

• Concomitant use of immunosupressants other than methotrexate or acitretin for psoriasis.

• Severe comorbidities with short life-expectancy (e.g. metastasized tumour).

• Presumed inability to follow the study protocol.

• Infliximab use

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5161
NTR-old	NTR5301
Other	ZonMw project : 80-83600-98-40024

Study results

Summary results

-