PDE4 inhibitor (apremilast) in pemphigoid

No registrations found.

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

Summary

ID

NL-OMON21799

Source
NTR

Brief title
SAMP trial

Health condition

Pemphigoid

Pemfigioid

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: Celgene

Intervention

Outcome measures

Primary outcome

Partial remission

Secondary outcome

Drug survival

Complete remission

Study description

Background summary

Pemphigoid is the most common chronic autoimmune disease of the skin and mucosae. It is often treated with systemic corticosteroids, which are associated with serious adverse effects. Therefore, there is a need for safer treatment options. In this pilot efficacy study the treatment response of apremilast combined with doxycycline in mild to moderate cutaneous pemphigoid of ten patients will be evaluated. The primary objective is partial remission, secondary objectives are drug survival and complete remission. Eligible patients will be recruited during routine clinical care in the department of Dermatology of the UMCG.

Study objective

Impairment of immune-complex-induced neutrophil activation caused by PDE4 inhibition, making it a potential target for the treatment of pemphigoid diseases.

Study design

Baseline and week 16

Intervention

Apremilast combined with doxycycline

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients with recently diagnosed mild to moderate localized or generalized cutaneous pemphigoid, or patients that were in complete remission without treatment that have a mild-moderate flare-up of the disease.

Exclusion criteria

Contradiction or known allergy for PDE4 inhibitors.

Women of childbearing potential without contraception, women who are pregnant or planning to become pregnant or who are lactating.

Patients that use systemic immunosuppressive medication

Any condition which would make the patient unsuitable for treatment, or requires steroid use.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-07-2018
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	NL7166
NTR-old	NTR7388
Other	Celgene : AP-CL-OTHER-PI-12868

Study results