Bullous versus nonbullous pemphigoid: what makes the blister?

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20573

Source
Nationaal Trial Register

Health condition

bullous pemphigoid, nonbullous pemphigoid, bulleus pemfigoïd, niet-bulleus pemfigoïd.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: International Pemphigus and Pemphigoid Foundation

Intervention

Outcome measures

Primary outcome

The difference in gene expression in nonbullous and bullous pemphigoid patients will be analyzed using principle component analysis. Furthermore, the expression levels of surface markers and proteins on eosinophils will be compared between the two pemphigoid variants.

Secondary outcome

not applicable

Study description

Background summary

Rationale: Pemphigoid is the most common autoimmune bullous disease and typically presents with severe itch and bullae on the skin (bullous pemphigoid). However, pemphigoid can also present without blisters, named nonbullous pemphigoid. Nonbullous pemphigoid can be difficult to recognize for doctors and results in a delay of treatment. To date, the exact pathogenesis of pemphigoid is still not completely unraveled, and it is unknown what causes the differences in phenotype.

Objective: The aim is to investigate the differences in pathogenesis of nonbullous and bullous pemphigoid by comparing gene expression, and the presence of activated and apoptotic eosinophils and IL-31 expression in skin, blood and blister fluid of both disease phenotypes.

Study design: prospective observational study

Method: 5 participants with nonbullous pemphigoid ≥ 18 years old and 5 participants with bullous pemphigoid ≥ 18 years old will be included. Gene expression will be assessed by RNA sequencing of one lesional and one healthy skin biopsy of the participants. Left over skin after surgery will be used as control skin of 4 persons ≥ 18 years old that do not suffer from pemphigoid. Moreover, a third biopsy will be taken of lesional skin for immunofluorescent staining to assess eosinophilic activity and IL-31 in the skin. Moreover, blister fluids will be collected in the patients with bullous pemphigoid, and a cytospin will be stained for IL-31 expression

Study objective

Difference in phenotype between nonbullous and bullous pemphigoid can be explained by gene expression and/or eosinophillic activity in the skin.

Study design

There is only one point of observation, at the moment that we take biopsies. There is no follow-up.

Intervention

no interventions will be used. we will collect biopsies from patients that are included.

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Eligibility criteria

Inclusion criteria

1. Written informed consent.

2. ≥18 years old.

3. Patients that are diagnosed with pemphigoid (bullous or nonbullous) ¡Ü1 month ago, or pemphigoid patients that were in complete remission without therapy and experience a relapse can be included.

[The following diagnostic criteria are used for pemphigoid: a positive DIF with linear IgG and/or C3c along the BMZ, and/or positive IIF on SSS or monkey esophagus, in combination with compatible clinical presentation, histopathological findings, or other immunoserological tests.]

If the criteria are fulfilled, patients will be categorized into the nonbullous phenotype (no history and no current blistering on the skin) or the bullous phenotype.

4. DIF results of the healthy skin biopsy (taken as normal procedure for diagnosis) must be positive in all patients.

5. Active disease with skin lesions.

Exclusion criteria

potential subject who meets any of the following criteria will be excluded from participation in this study:

1. The use of systemic immunosuppressive medication, such as prednisolone (>0.3mg/kg/day), methotrexate, azathioprine or dapsone (see guideline Feliciani et al)5 within the last 4 weeks before the sample collection. Prednisolone in a dosage ¡Ü 0.3 mg/kg/day is allowed.

2. Application of topical potent corticosteroids on the skin within the last week.

3. cognitively incompetent (psycho)geriatric patients

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-04-2018
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	NL6971
NTR-old	NTR7159
Other	METc : 2017/653

Study results