Bullous versus nonbullous pemphigoid: what makes the blister?

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20573

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: International Pemphigus and Pemphigoid Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-04-2018
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	NL6971
NTR-old	NTR7159
Ander register	METc : 2017/653

Resultaten