

Pruritus and pemphigoid in nursing home patients

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Pruritus or itch is the most common skin symptom in elderly patients and is estimated to affect more than 30% of nursing home patients. Clinical and experimental evidence suggests pruritus in elderly patients may be linked to pemphigoid. Pemphigoid...

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

Samenvatting

ID

NL-OMON26576

Bron

NTR

Verkorte titel

SSENIOR

Aandoening

Pruritus, itch, pemphigoid, autoimmune bullous diseases, dementia, neuropsychiatric symptoms

Jeuk, pemfigoïd, auto-immuun blaarziekten, dementie, neuropsychiatrische symptomen

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Presence and intensity of pruritus:

Intensity will be scored with the Bullous Pemphigoid Disease Area Index (BPDAI) pruritus score, which is a Visual Analogue Scale (VAS) from 0 (no itch) to 10 (maximum itch).

Additionally, presence and intensity of pruritus will be determined hetero-anamnestically in all patients based on the derivative score of the extent of excoriations in the BPDAI pruritus score. Other present skin lesions will be classified using the ILDS skin efflorescence classification (e.g. excoriations, blisters, vesicles, papules, urticarial, erythema), other relevant skin diseases will be registered from the medical record.

- Pemphigoid immunoserology:

- Indirect IF on monkey esophagus substrate: anti-basement membrane zone (BMZ) IgG antibodies

- Indirect IF on human salt-split skin substrate

• IgG antibodies with epidermal side staining of artificial split: positive/ negative

- ELISA BP180 NC16A: anti-BP180 NC16A IgG index (cut-off value positive ≥9 U/ml)

- ELISA BP230: anti-BP230 IgG index (cut-off value positive ≥9 U/ml)

- Immunoblot keratinocyte extract: presence of circulating IgG antibodies against BP180 (180kDa) or BP230 (230 kDa)

Toelichting onderzoek

Achtergrond van het onderzoek

Hypothesis: Pruritus or itch is the most common skin symptom in elderly patients and is estimated to affect more than 30% of nursing home patients. Clinical and experimental evidence suggests pruritus in elderly patients may be linked to pemphigoid. Pemphigoid is the most common autoimmune skin blistering diseases and mainly affects the elderly. It is successfully treatable with systemic therapy. However, pemphigoid is often missed as a cause of pruritus in elderly patients. Although nursing home patients and patients with dementia in particular have the highest risk for development of pemphigoid, no study has been performed in this population so far. Including serological screening for pemphigoid in the diagnostic evaluation of chronic pruritus in nursing home patients may lead to the diagnosis of pemphigoid. Furthermore, chronic itch may be an unrecognized cause of neuropsychiatric symptoms in nursing home patients with dementia.

Objective: to determine the prevalence of pruritus and pemphigoid in nursing home patients.

Study design: cross-sectional study.

Study population: nursing home patients aged 65 years or above, living in a nursing home of

one of the long-term care organisations participating in the Universitair Netwerk Ouderenzorg (UNO-UMCG).

Invasive procedure: one extra blood sample of 10 ml will be taken for immune serological testing during a routine venapunction.

Main study parameters/endpoints: the main study outcome is the prevalence of pruritus and pemphigoid in nursing home patients. Intensity of pruritus is scored with the BPDAl pruritus score and a derivative score of skin excoriations. Secondary outcomes are the relationships of demographic factors and medical risk factors with pemphigoid, including dementia and neuropsychiatric symptoms, medication use and Karnofsky activity of daily living score.

Doel van het onderzoek

Pruritus or itch is the most common skin symptom in elderly patients and is estimated to affect more than 30% of nursing home patients. Clinical and experimental evidence suggests pruritus in elderly patients may be linked to pemphigoid. Pemphigoid is the most common autoimmune skin blistering diseases and mainly affects the elderly. It is successfully treatable with systemic therapy. However, pemphigoid is often missed as a cause of pruritus in elderly patients. Although nursing home patients and patients with dementia in particular have the highest risk for development of pemphigoid, no study has been performed in this population so far. Including serological screening for pemphigoid in the diagnostic evaluation of chronic pruritus in nursing home patients may lead to the diagnosis of pemphigoid. Furthermore, chronic itch may be an unrecognized cause of neuropsychiatric symptoms in nursing home patients with dementia.

Onderzoeksopzet

Cross-sectional

Onderzoeksproduct en/of interventie

Intervention not applicable.

Invasive procedure: one extra 10mL blood sample will be taken during a routine venapunction

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Inpatient of a nursing home (UNO-UMCG)
- Age \geq 65 years
- Subjects or their official representatives have signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:

- Age < 65 years
- Subjects who do not have signed informed consent

- Receiving treatment with (any) systemic immunosuppressive agents
- Terminally ill patients with a life expectancy of less than 4 weeks

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	15-06-2016
Aantal proefpersonen:	126
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	03-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43546
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5604
NTR-old	NTR5843
CCMO	NL56232.042.15
OMON	NL-OMON43546

Resultaten