

Pruritus and pemphigoid in nursing home patients

No registrations found.

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

Summary

ID

NL-OMON26576

Source

Nationaal Trial Register

Brief title

SSENIOR

Health condition

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

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

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

- 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)

Secondary outcome

- Age, sex
- Co-morbidities
- Dementia (according to DSM IV-criteria)
- Cerebrovascular accident
- Parkinson's disease
- Other neurodegenerative disease
- Neuropsychiatric symptoms: Neuro Psychiatric Inventory – Nursing Home version (NPI-NH, hetero-anamnesic)
- Activities of Daily Living: Karnofsky Performance Scale)
- Medication use (medical file)

Study description

Background summary

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.

Study objective

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.

Study design

Cross-sectional

Intervention

Intervention not applicable.

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

Contacts

Public

Hanzeplein 1

Joost M. Meijer
PO box 30.001

Groningen 9700RB
The Netherlands

Scientific

Hanzeplein 1

Joost M. Meijer
PO box 30.001

Groningen 9700RB
The Netherlands

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-06-2016
Enrollment:	126
Type:	Anticipated

Ethics review

Positive opinion

Date: 03-06-2016

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43546

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results