Impact of dementia-related neurodegeneration on pain processing

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON47032

Source
ToetsingOnline

Brief title
Pain processing in dementia

Condition

- Central nervous system vascular disorders
- Dementia and amnestic conditions

Synonym
Alzheimer desease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Huisartsgeneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dementia, neurodegeneration, pain

Outcome measures

Primary outcome

Response to various mild pain stimuli (pressure pain will be applied to the

shoulder and temperature (heat) will be applied to the forearm)

- Self -report

- Facial expression (the face will be videotaped and analyzed using the Facial

Action Coding System)

- Heartrate and heartrate-variability

Secondary outcome

- structural MRI (grey and white matter (especially in frontal areas))

- Neuropsychology testing (attention, memory, executive functioning)

Study description

Background summary

It is widely acknowledged that pain management for patients with dementia is inadequate, with many patients suffering from pain unnoticed and untreated. This is due to the loss of verbal communication skills over the course of dementia, with patients losing the ability to report about pain and thereby, making it more challenging to assess and adequately treat pain. Besides dementia affecting the communication of pain, there is also evidence that the pain system itself might be altered across the course of dementia. So far, only a few studies have been conducted that used experimental pain to investigate nociceptive processing in patients with dementia (mostly in patients with mild or moderate degrees of Alzheimer*s disease) and alarmingly found increased responses to pain. Thus, patients with dementia might face the dilemma of being more sensitive to pain compared to cognitively unimpaired individuals, while at the same time being less able to verbally report about their pain. In order to reduce unnecessary suffering from pain, exploring the manner by which

individuals with dementia process, experience and respond to pain is an imperative ethical goal.

Study objective

The objective is to investigate how dementia affects processing of pain. More precisely, we aim to investigate how dementia-related neurodegeneration (occurring in Alzheimer disease (AD), frontotemporal dementia (FTD) and vascular dementia (VD)) affects ascending and descending pain processes.

Study design

In order to investigate ascending and descending mechanisms of pain processing, different experimental pain paradigms will be conducted in patients with AD, FTD and VD that allow for investigating endogenous pain inhibitory mechanisms as well as pain facilitation mechanisms. For this purpose, pressure and heat stimuli of mild pain intensities will be applied and subjective, facial, motor and autonomic responses will be assessed. Pain responses will then be related to structural changes in grey and white matter using MRI (magnetic resonance imaging).

Study burden and risks

This study entails no risk to the participant. The experimental pain is non-invasive, of slight intensity and of short duration. Nevertheless, the pain induction will be accompanied with unpleasant experiences, although they are of short duration. Extra effort and care will be undertaken to monitor the participants carefully for any signs of discomfort and stress and testing will be immediately stopped if signs are present. The subjects will visit the Neuroimaging Center (NIC) for the structural scan and the neuropsychological testing (60 minutes) and will return for the experimental pain session (30 minutes). The investigation can contribute to a better understanding how pain processing is altered in different types of dementia, which will be very relevant for pain management strategies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:;All subjects:
- Age from 55 * 85 yr
- Willingness to cooperate and sign written informed consent * or proxy consent with assent of participating subject;Normal Healthy Controls (CP):
- MMSE scores between 27-30
- Without subjective memory complaints;Alzheimers*s disease dementia (AD):
- Diagnosis of probable AD according to the Alzheimer*s disease and Related Disorders Associations (NINCDS-ADRDA) criteria and NIA-AA guidelines (McKhann et al. 2011).;Frontotemporal dementia (FTD):
- Diagnosis of behavioral variant FTD (FTD-b) according to the revised consensus criteria (Rascovsky et al. 2011).
- Diagnosis of a subtype of FTD of Primary Progressive Aphasia (PPA), divided into Semantic Dementia (SD), Progressive Nonfluent Aphasia (PNFA) and LPA due to FTD (Gorno-Tempini et al. 2011). ;Vascular dementia (VD):
- Diagnosis of probable VD according to the NINDS-AIREN (National Institute of Neurological Disorders and Stroke and the Association Internationale pour la Recherche et l*Enseignement en Neurosciences) guidelines (Roman et al. 1993).

Exclusion criteria

All subjects:
- History of major psychiatric illness
- Medications which may affect pain processing (selective serotonin re-uptake inhibitors, opioids, other analgesics)
- Contraindications for MR-measurements (e.g. cochlear implants and most permanent pacemakers, red tattoos);Normal healthy Controls:
- abnormal results on neuropsychological tests
- subjective memory complaints;All patients:
- Cognitive deficits could be explained by non-neurodegenerative condition (e.g. stroke, neoplasm, head injury, hydrocephalus or other medical condition)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2016
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO

Date:	25-11-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	08-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL58624.042.16