The 90+ Study

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

Samenvatting

ID

NL-OMON25600

Bron
NTR

Verkorte titel
90+ Study

Aandoening

Alzheimer, dementia, ageing, oldest old

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: EMIF-AD

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objectives are:
1. To understand how clinical markers and biomarkers previously identified (and published) in younger and older dementia cohorts apply to the extreme elderly.
2. To identify novel biomarkers linked with resilience to developing AD in extreme elderly

subjects.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: It is estimated that 35.6 million people over age 60 years lived with dementia worldwide in 2010. In the US, the oldest old individuals (85+ years old) represent the fastest growing segment of the population; the number of oldest old living with dementia in the US could grow from 1-2 million in 2010 to more than 8 million by 2050 or 2060. Thus, improved diagnostic criteria and neuropsychological norms are urgently needed to ensure accurate diagnosis in this specific population. A full understanding of the prevalence of dementia among the oldest old of different socioeconomic, ethnic, and racial backgrounds is also required. Of specific interest to us is the need to gain a better understanding of the characteristics/traits/biomarkers associated with resilience to dementia to a fraction of the oldest old who are able to maintain age appropriate cognitive function.
Patients/volunteers will be asked to participate in a study evaluating their cognitive function, amyloid load (analysis of biomarkers in the CSF obtained via lumbar puncture and amyloid PET imaging), genotyping, and phenotyping across a number of visits.

Objective: The main objectives are to understand how clinical markers and biomarkers previously identified in younger and older dementia cohorts apply to the extreme elderly (90+ years old) and to identify novel biomarkers linked with resilience to developing Alzheimer’s disease (AD) in extreme elderly subjects.

Study population: We will enrol 60 cognitively normal subjects and 60 subjects suffering from cognitive impairment, 90+ years old, from EHR, the Manchester and Newcastle Aging Study (MNAS), and the VUmc.

Main study parameters/endpoints: The main outcome is the identification of clinical, biochemical, and genetic factors associated with resilience to cognitive decline in extreme elderly subjects. At baseline we will test the association between cognitive resilience and amyloid aggregation, neuropsychological, clinical, and physical markers, brain connectivity as assessed by electroencephalography (EEG), magnetoencephalography (MEG) or Magnetic Resonance Imaging (MRI), brain atrophy as assessed by MRI, vascular changes as assessed by MRI, retinal imaging or duplex of the carotid arteries, genetic markers, and CSF and blood (plasma, serum, RNA, DNA) markers.

Doel van het onderzoek

The main outcome is the identification of clinical, biochemical, and genetic factors associated with resilience to cognitive decline in extreme elderly subjects. At baseline we will test the association between cognitive resilience and amyloid aggregation, neuropsychological, clinical, and physical markers, brain connectivity as assessed by electroencephalography

(EEG), magnetoencephalography (MEG) or Magnetic Resonance Imaging (MRI), brain atrophy as assessed by MRI, vascular changes as assessed by MRI, retinal imaging or duplex of the carotid arteries, genetic markers, and CSF and blood (plasma, serum, RNA, DNA) markers.

Onderzoeksproduct en/of interventie

None

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

To be eligible for this study, candidates must meet all of the following criteria:

• Age ≥ 90 years

• Candidate is able to walk 400 meter independently (with or without walking aid)

• No significant visual or hearing impairment (as judged by clinician)

Cognitively intact group (cases):

o MMSE ≥ 27 points

o Clinical Dementia Rating (CDR) = 0.0 points

Demented group (control):

o MMSE: 20-28 points inclusively

o Clinical Dementia Rating (CDR) ≥ 1 point(s)

o Determination that this dysfunction is due to cognitive functional loss and not physical impairment, as judged by a neurologist or internist-geriatrician.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

• Clinical diagnosis of severe AD

• Severe head trauma, with loss of consciousness

• Brain tumour (past, present)

• Schizophrenia, bipolar disorder, or recurrent psychotic disorders

• Stroke resulting in physical impairment

• Non-AD neurodegenerative disorders (e.g. Huntington disease, cortical basal degeneration, multiple system atrophy, CreutzfeldtJacob disease, primary progressive aphasia, Parkinson's disease, diffuse Lewy body disease, frontotemporal dementia, primary vascular dementia)

• Epilepsy, currently using antiepileptic drugs (AEDs)

• Brain infections (e.g. herpes simplex encephalitis)

• Cancer with terminal life expectancy (life expectancy <12 months)

• Cancer chemotherapy or radiotherapy within the last 3 months

• Known B12 vitamin deficiency without treatment

• Uncontrolled diabetes mellitus (last measure HbA1c >80 mmol/mol)

• Known thyroid disease without treatment

• History of recreational drug use

• Alcohol consumption: >35 units per week (1 unit = 10ml of pure alcohol)

• Physical morbidity or illness which will not permit attendance at visit sessions

• Contraindication for MRI (e.g. metal implants, pacemaker etc.)

• Medications that may impair cognition, at the discretion of the investigator, e.g.:

o Benzodiazepine with known effects on cognitive functioning

o Lithium carbonate

o Antipsychotics including atypical agents

o Antidepressants with known effects on cognitive functioning

o Parkinson’s disease medicines

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-05-2016
Aantal proefpersonen:	74
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-05-2016
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	NL5714
NTR-old	NTR5867
Ander register	NL53756.029.15 : 2015.374

Resultaten