Models of Patient Engagement for Alzheimer's Disease

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MOPEAD will compare the four different subpopulations with regard to detection of hidden cases of mild cognitive impairment (MCI) due to AD or mild AD dementia using an extensive evaluation of selected individuals using cognition, biomarkers, and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON48863

Source
ToetsingOnline

Brief title
MOPEAD

Condition

- Neurological disorders NEC

Synonym
Alzheimer's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Eli Lilly,IMI (Innovative Medicine Initatives)

Intervention

Keyword: Alzheimer's disease, Early diagnosis, Risk of AD, Subpopulations

Outcome measures

Primary outcome

Risk for Alzheimer dementia, based on extensive evaluation using cognition, biomarkers, and traditional risk factors (genetic and environmental).

Secondary outcome

To compare the cost-effectivity (of recruitment and pre-screening) of four different subpopulations to detect individuals with prodromal/mild AD dementia within the Netherlands. In addition, cost-effectivity will be compared with findings in the other participating sites in other European countries.

Study description

Background summary

Several health economic studies carried out in different countries showed that identifying AD individuals at an early stage (MCI due to AD or mild AD dementia) results in cost savings and health benefits compared with no treatment or treatment in the absence of early assessment. Besides, the disappointing results of clinical trials carried out in individuals with dementia have given rise to the idea that interventions have occurred too late in the disease process. Therefore, from the drug development point of view an early diagnosis is critically needed to identify optimal candidates for new clinical trials. Currently, it is unknown how these subjects at high risk of AD but without dementia can efficiently be detected in the general population. In this context there is a clear need to test and compare existing and innovative patient engagement models. Four subpopulations will be evaluated: 1) participants who sign up for participating via an online platform; 2) participants that visited an open house or event; 3) participants recruited via primary care practitioners (GP); 4) participants recruited via tertiary care based specialists (endocrinologist office).

Study objective

MOPEAD will compare the four different subpopulations with regard to detection of hidden cases of mild cognitive impairment (MCI) due to AD or mild AD dementia using an extensive evaluation of selected individuals using cognition, biomarkers, and traditional risk factors (genetic and environmental) and compare this between five European countries.

Study design

This is a cross-sectional, observational, pan-European, multicenter (Netherlands (VUmc); Spain (FACE); Sweden (Karolinska Institute); Slovenia (SPO); Germany (University of Köln)) study. The protocol of this study is identical for all participating countries/centers.
Each site will obtain local IRB approval. MOPEAD is a European multi-country project approved and supported by the Innovative Medicines Initiative (IMI). It will be carried out by a consortium of 14 members (Table 1), including academic institutions, pharmaceutical industry, technological companies and relevant stakeholders such as patient associations, as shown below.

Duration of the study
The study includes 1 visit that takes place at the Alzheimer center of the VU Medical Center with a duration of approximately 5 hours. The visit is described in more detail in chapter 5.2.

Follow-up from Prescreening protocol (METc 2018.057)
The Prescreening phase of this protocol will be performed under a separate protocol (METc 2018.057). During prescreening, non-demented participants will be recruited from four different subpopulations: 1) participants who sign up for participating via an online platform; 2) participants that visited an open house or event; 3) participants recruited via primary care practitioners (general practitioners); 4) participants recruited via tertiary care based specialists (endocrinologists office). This screening consists of a short neuropsychological test and several questionnaires. Based on the data of each participant of the prescreening, we will check for inclusion- and exclusion criteria for MOPEAD (this protocol).

Study burden and risks

The visit at VUmc will take approximately 5 hours, including neurological examination, neuropsychological assessment, blood sampling, APOE genotyping and MRI. Optionally, CSF sampling will be performed. All procedures used in this study are medical routine procedures, therefore the risks are negligible.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HZ
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- aged between 65-85 years.
- without a previous diagnosis of cognitive impairment
- a reliable informant
- capable to speak Dutch;Additional criteria applied for the specific subpopulations:
Subpopulation 1) Online
* - Visitors of the online platform
* - CANTAB score below the pre-fixed cut-off (adjusted by age and education) on the online cognitive tests. The cut-off will be determined in association with Cambridge Cognition based on already collected data in participants with normal cognition, MCI and dementia.;Subpopulation 2) Open house or event
* - Visitors of an open house or event which are recruited by advertisements or via Hersenonderzoek.nl.
* Any of the following:
- MMSE between 20-27 or
- FSCRT total score <1.5 SD below the normal score for age and education or

- FCSRT total score between 1 * 1.5 SD + 3 positive answers to SCD questions.;Subpopulation 3) Primary care
* - Patients visiting their GP.
* - Individuals with available data in the medical records needed for calculate CAIDE Dementia Risk Score and check out the exclusion criteria.
* Any of the following:
- MMSE between 20-27 or
- New CAIDE risk score suggesting high risk of dementia.
- New CAIDE Risk Score suggesting medium risk of dementia + 3 positive answers to SCD questions.;Subpopulation 4) Tertiary care
* - Patients visiting the endocrinology department of VUmc.
* - With a diagnosis of type 2 diabetes mellitus.
* Individuals with available data in the medical records needed for calculate DSDRS (reliable data on the medical records regarding: age, level of education, history of acute metabolic events, history of diabetic foot, history of microvascular disease, history of cerebrovascular disease, history of cardiovascular disease, diagnosis of depression) and check out exclusion criteria.
* - Reliable data on microalbuminuria and funduscopy of the 12 previous months.
* - At least 2 determinations of HbA1c in the 2 previous years.
* Any of the following:
- MMSE between 20-27 or
- DSDRS> 10
- DSDRS 7-10 + 3 positive answers to SCD questions.

Exclusion criteria

- Severe visual or hearing impairment that could interfere with the assessment.
- History of traumatic brain injury involving loss of consciousness.
- History of stroke (symptoms lasting more than 24 hours), epilepsy, demyelinating disease, parkinsonism, CNS infection.
- Current symptoms of major depression.
- Presence of severe metabolic or systemic disease that could be responsible for the cognitive symptoms in the opinion of the investigator.
- Treatment with psychotropic medications that could significantly interfere with cognition in the opinion of the investigator.
- A previous diagnosis of cognitive impairment.
- Any contraindication to undergo MRI (claustrophobia, incompatible pacemakers, metallic medical devices, etc).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2018
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL63046.029.17