Novel diagnostic approaches for the diagnosis of Alzheimer's Disease: Technology assessment and clinical effectiveness.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON36838

Source
ToetsingOnline

Brief title
Health technology assessment of diagnostic approaches in AD.

Condition

- Structural brain disorders

Synonym
Alzheimer's disease, Dementia, Neurodegenerative disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: CTMM

Intervention

Keyword: Alzheimer's disease, Benefits, Costs, Diagnosis

Outcome measures

Primary outcome

- Biomarkers in liquor

- Magnetic Resonance Imaging (MRI)

Disease severity:

- MMSE

- CDR

Quality of life:

- Euro-Qol-5D (patient and caregiver)

- QoL-AD (patient and caregiver)

Costs:

- RUD-Lite

- ProDisq

- Other resource use

- Health and labour questionnaire

Secondary outcome

- Demografic and administrative data

- General clinical data

Patient questionnaires:

- NPI

- DAD

- GDS-15

Neuropsychological tests

Caregiver burden:

- SoCQ

- CareQol

Study description

Background summary

Many diagnostic procedures have been developed and applied on patients with dementia, in which most diagnoses are based on clinical judgment and neuropsychological testing. In recent years, many efforts have been made to develop more accurate and less time consuming biotechnical diagnostics, including brain imaging (MRI, PET) and markers in CSF. These diagnostics however, are not recommended as part of the routine workup for people with suspected dementia. Furthermore, the diagnostic added-value of these techniques has not been established yet. There needs to be an economic model to validate and assess the accuracy, quality of life and costs of those new techniques. Moreover, costs and benefits of these tests need to be compared with the tests of the current clinical standard, and besides that, the model should take into account the advantages of an earlier diagnosis with relation to Alzheimer*s disease.

Study objective

The general objective is to validate and assess the clinical and economic added-value of a) innovative diagnostic tests developed in WP1 (PET tracers), WP2 (ultra high field MRI) and WP3 (CSF), and b) other emerging diagnostic tests for Alzheimer's Disease vis-a-vis the diagnostic work-up that is the

current clinical standard, and c) to develop a 'decision analytic model' that can be used to integrate the data from a) and b).

Study design

Prospective cohortstudy.
The regular diagnostics of patients visiting the memoryclinics is arranged in a way that the data, which are gathered in a standardized manner during the diagnostic process, are unambiguously saved. This enables exchange of data between the participating Academic Medical Centres (UMC's). In consultation with each other, the responsible participants of those UMC's have established a minimal dataset, to be registered at some specified moments in time (baseline and follow-up). This dataset consists of data that already are collected during the common healthprocess, but not always in a standardized way. The standardisation is about both the way data are collected and of registering it in a database. Even though the type of healthcare remains the same, it might be necessary to adjust the organisation of the healthcare pathway to meet the needs of standardisation.
The gathering of data will be prospective and (in part) longitudinal, with a follow-up once a year. Expectation is that inclusion will start in 2009, with an open end.
Additional liquor (3ml) will be gathered and registered in a biobank, adapted to the regular acquisition of bodily material as much as possible. This additional material will be collected during baseline. It will be centrifuged, ... (uitgevuld in 0.5ml cryovials) and stored by a temperature of -80 degrees Celcius. The bodily material will be encoded and stored in the biobanks of the participating UMC's.

Study burden and risks

Liquor: there is great vagueness about the involved risk of lumbal punctures. However, this risk seems to be considerably negligible, as it turns out that with the use of a thin a-traumatical needle the chance of getting a postpunctional headache (the most probable complication) is reduced to less than 10%. The amount of liquor that is taken is of no account, as long as it remains less than 30ml. Patients suffering from Alzheimer's Disease or mild cognitieve impairments even show a smaller risk, that is, less than 2%. Moreover, they also seem to be less troubled by pain during the puncture. Other complications like meningitis and subdural spinal haematoma are extremely uncommon (Peskind ER, Alz Dis Assoc Disord 2005; 19:220-225).
MRI: patiens and caregivers will not be exposed to invasive methods or other risky cirumstances. MRI scans are performed mainly as part of the regular healthcare package.

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

- All new consecutive patients of the participating memory clinics who are suspected of having a primary neurodegenerative disease. This means all patients with subjective and/or objective memory complaints.
- CDR 0, 0.5 or 1
- Mini Mental State Examinations (MMSE) score must be 20 or higher.
- Availability of a reliable informer or proxy (who visits or contacts the patient at least once a week).

Exclusion criteria

- Normal Pressure Hydrocephalus (NPH)

- Huntington's disease
- Recent Transient Ischaemic Attack (TIA) (<2 years) or Cerebral Vascular Accident (CVA) or TIA/CVA followed by cognitive impairment (within 3 months)
- History of Schizophrenia, other psychotic disorders (< 12 months)
- Major depression (< 12 months)
- Alcohol abuse
- Brain-tumor, epilepsy, encephalitis
- Absence of a reliable informant
- Probably not available for follow-up

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-06-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-07-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-08-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL25214.068.09

Study results

Date completed: 01-04-2015

Actual enrolment: 251