Aging-related memory impairment: a behavior-genomics study

Published: 26-09-2016
Last updated: 17-04-2024

The current study is part of a larger project that aims at identifying genetic profiles that render subject vulnerable to pronounced memory decline at old age. This part of the project will assess cognitive functions in three different age cohorts...

Ethical review	Not approved
Status	Will not start
Health condition type	Structural brain disorders
Study type	Observational invasive

Summary

ID

NL-OMON43432

Source
ToetsingOnline

Brief title
Memory genomics

Condition

- Structural brain disorders

Synonym
No disorder: Age-related memory performance

Research involving
Human

Sponsors and support

Primary sponsor: Takeda
Source(s) of monetary or material Support: door de sponsor: Takeda (farmaceutische industrie)

Intervention

Keyword: Age cohorts, Cognition, Genomics, Memory

Outcome measures

Primary outcome

The primary outcome measure is memory decline in the Verbal Learning Test (VLT).

Secondary outcome

In the eldest group, the Mini Mental State Examination will provide a more global indication on cognitive functioning. For all groups, functioning in related cognitive domains will be assessed using the Visual Association Test, Digit Span, Fluency, Letter Digit Substitution, Stroop, Trail Making Test, and Pattern Separation.

Study description

Background summary

Memory impairment is more pronounced in people with a particular genetic make-up. Rare cases of familial dementia can be attributed to single gene mutations. However, in the majority of cases multiple genes contribute to an increased risk and interact in ways not well understood.

Study objective

The current study is part of a larger project that aims at identifying genetic profiles that render subject vulnerable to pronounced memory decline at old age. This part of the project will assess cognitive functions in three different age cohorts on three time points (once per year). Blood samples will be drawn at each time point to link the genetic profile with cognitive performance.

Study design

The study is conducted according to a longitudinal design (2 year follow-up) in three age cohorts (18-30, 40-60, 60-80 years old). Subjects will be asked to visit the laboratory once a year during which a standardised cognitive battery will be applied. The genomics (RNA) and genetics (DNA) parameters obtained from the blood samples obtained at every visit will be linked to cognitive performance.

Study burden and risks

This study involves minimal risks for the subjects. Time investment will be around 5 hours in total. It is possible subjects will feel somewhat tired due to the test procedures and blood sampling can be perceived as painful and can result in bruises.

Contacts

Public
Takeda

One Takeda Parkway 00
Deerfield IL 60015
US
Scientific
Takeda

One Takeda Parkway 00
Deerfield IL 60015
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. The subject has to sign and date a written informed consent form prior to the initiation of study procedures;
2. The subject falls in the age-range of one the cohorts, i.e. 18-30; 40-60; 60-80;
3. The subject has good comprehension of the Dutch language
4. Normal memory performance

Exclusion criteria

- Suffering from uncontrolled, clinically significant neurologic disease or other abnormality which may impact the ability of the subject to participate or potentially confound the study results, which includes pregnancy and having received chemo treatment during the past year.
- The presence of psychiatric illness including schizophrenia, depression, bipolar disorder, Attention Deficit Hyperactivity Disorder and autism;
- Smoking more than 10 cigarettes a day.
- Excessive drinking, i.e. >20 glasses of alcohol containing beverages a week,
- Current use of psychoactive medication (e.g. antidepressants, antipsychotics), centrally acting beta blockers, use of recreational drugs from 2 weeks before until the end of the yearly testing ,
- Any sensory or motor deficits which could reasonably be expected to affect test performance.
- Consultation of a clinical expert for memory problems before having entered the study
- Having received any investigational compound within 60 days prior to the Baseline (Screening) Visit

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	220
Type:	Anticipated

Ethics review

Not approved

Date:	26-09-2016
Application type:	First submission
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	NL56073.068.16