The ACER-study - the effects of galantamine on the variability and stability of walking among patients with Alzheimer's disease.

Published: 11-01-2012
Last updated: 30-04-2024

To examine the effects of treatment with galantamine among patients with AD on the variability and stability of walking (with and without dual-task), functional mobility, standing balance, and cognitive functions (e.g. attention and executive...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Aural disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35628

Source
ToetsingOnline

Brief title
The ACER-study

Condition

- Aural disorders NEC
- Dementia and amnestic conditions

Synonym
Alzheimer's disease; dementia

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Slotervaartziekenhuis zelf (Stichting Klinisch Wetenschappelijk Onderzoek Slotervaartziekenhuis - SKWOSZ)

Intervention

Keyword: Acetylcholine esterase inhibitors, Alzheimer's disease, Executive function, Gait variability & stability

Outcome measures

Primary outcome

The outcome variables of three balance assessments with accelerometry (with and

without dual-task) the 160-meter walking test, the Timed Up & Go test (TUG),

and the FICSIT-4 test.

Secondary outcome

Secondary outcome measures are: visual reaction time (indicator for attention),

cognition (Mini Mental State Examination, 7 Minute Screen, Frontal Assessment

Battery, STROOP color word test, and Digit Span), activities of daily living

(by IDDD), and fall events.

Study description

Background summary

Acetylcholine esterase (AChE) inhibitors are current symptomatic treatments for patients with Alzheimer's disease (AD). It is known that the performance of attention-demanding dual task increases gait variability and walking instability in elderly with cogntive impairments. Given that AChE inhibitors improve attention and executive function in patients with AD, it is hypothesized that treatment with the AChE inhibitor galantamine would improve cognitive dual-task-related changes in gait variability and stability among patients with AD.

Study objective

To examine the effects of treatment with galantamine among patients with AD on the variability and stability of walking (with and without dual-task), functional mobility, standing balance, and cognitive functions (e.g. attention and executive functions). Furthermore, the relation between variability and stability of walking with and without dual-tasking, and cognitive functions (e.g. attention and executive functions), and activities of daily living, will be examined.

Study design

Non-random controlled intervention study with a multiple A0A1B1A2A3 time series design with a duration of 12 months.

Intervention

Treatment with galantamine, by regular titration schedule.

Study burden and risks

There are no risks for patients to participate in the present study. Since treatment with galantamine is indicated by the patient's doctor, participation to the present study will not lead to extra risks for the patient. The treatment given by the patient's doctor is the same, whether patients are participating in the present study or not. Furthermore, the patient's burden is reduced to a minimum, since pre- and post-measurements will take place at the hospital during regular visits, and during the intervention period patients will be visited at home for balance assessments. Per visit at the hospital, it will take about 2 hr (maximum) to assess the tests. Assessments at the patient's home, will take about 30 minutes.

Contacts

Public
Slotervaartziekenhuis

Louwesweg 6
1266 EC Amsterdam
NL
Scientific
Slotervaartziekenhuis

Louwesweg 6

1266 EC Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients will be included for the present study when they are (a) aged 65 years or older; (b) diagnosed with mild to moderate Alzheimer's disease (according to the criteria of the DSM-IV and the NINCDS-ADRDA); and (c) able to walk for at least 160 meter without using any assistive device.

Exclusion criteria

Patients will be excluded from the present study when they (a) have had any treatment with acetylcholine esterase inhibitors during the three months before inclusion; (b) have any mobility problems due to (lateral) neurological or orthopedic disorders with function limitations of one or both legs; (c) have severe visual impairments; or (d) are unable to understand and follow simple verbal instructions.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	galantamine
Generic name:	galantamine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-01-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Approved WMO Date:	08-02-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
EudraCT	EUCTR2011-006011-62-NL
CCMO	NL38747.048.11