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A study to assess the benefits and safety of a once-daily special ginkgo biloba extract (EGb 761) in people with dementia who also have psychological or behavioural problems

Submission date
25/11/2026

Recruitment status
No longer recruiting

Registration date
26/11/2026

Overall study status
Completed

Last Edited
26/11/2026

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Dementia can affect memory, thinking, behaviour and emotions. Many people with dementia also experience psychological or behavioural symptoms such as anxiety, agitation, irritability or loss of interest in activities. Ginkgo biloba is a plant that has been studied as a possible treatment for symptoms of dementia. This study aimed to find out whether a special ginkgo biloba extract called EGb 761 could safely improve thinking, memory and behavioural symptoms in people with Alzheimer's disease or vascular dementia.

Who can participate?
People aged 50 to 100 years with mild to moderate Alzheimer's disease or vascular dementia could take part. Participants had to have experienced symptoms of dementia for at least 6 months and have psychological or behavioural symptoms related to their condition.

What does the study involve?
Participants were randomly assigned to receive either a once-daily tablet containing 240 mg of the ginkgo biloba extract EGb 761 or a placebo tablet that looked the same but contained no active ingredient. Neither the participants nor the study team knew which treatment each person received during the study.
Treatment lasted for 24 weeks. Participants attended study visits where their memory, attention and thinking abilities were assessed using standard tests. Their psychological and behavioural symptoms were also evaluated using questionnaires completed with the help of carers or healthcare professionals. Participants underwent safety assessments, including medical examinations, checks of vital signs, heart monitoring, laboratory tests and recording of any side effects or health problems that occurred during the study.

What are the possible benefits and risks of participating?
Participants receiving EGb 761 may have experienced improvements in memory, thinking abilities or behavioural symptoms, although this could not be guaranteed. Information collected

during the study may help improve the treatment of people with dementia in the future.
As with any medicine, there was a risk of side effects. Participants also had to attend study visits and complete assessments, which could take time and may have been tiring. Their health was carefully monitored throughout the study to help identify any problems.

Where is the study run from?
The study was run by Dr. Willmar Schwabe GmbH & Co. KG in Karlsruhe, Germany. Participants were recruited from study centres in Ukraine.

When is the study starting and how long is it expected to run for?
April 2006 to December 2007.

Who is funding the study?
Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany.

Who is the main contact?
Dr Robert Hoerr
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Sponsor-ID
523001.01.075

Study information

Scientific Title
Randomised, double-blind, placebo-controlled, parallel-group, multicentre trial to confirm the efficacy, safety and tolerability of a once-daily formulation of ginkgo biloba special extract EGb 761 in patients suffering from Alzheimer's disease or vascular dementia, both associated with neuropsychiatric symptoms

Acronym
GOT-A-DAY

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/12/2005, Ethic Committee of the State Pharmacological Centre (Central Ethics Committee of the Ministry of Health of Ukraine) (Ministry of Health, Ukraine, Kiev, 01021, Ukraine; +380 44 2532444; dec@dec.gov.ua), ref: 5.12-523/KE

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Alzheimer's disease or vascular dementia, both associated with neuropsychiatric symptoms

Interventions
1 x 1 tablet 240mg EGb 761® or placebo oral for 24 weeks. Randomisation (1:1, stratified by centre and in blocks of four), was performed with the aid of avalidated computer program that linked random numbers todrug or placebo treatment, respectively.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Ginkgo biloba special extract EGb 761®

Primary outcome(s)
1. Cognitive impairment measured using the total scores of the Syndrom-Kurz-Test (SKT, cognitive domain) and the Neuropsychiatric Inventory (NPI; neuropsychiatric domain) at baseline, week 12 and week 24

Key secondary outcome(s)
1. Safety measured using laboratory tests at screening visit and week 24

2. Tolerability measured using adverse events at baseline, week 6, week 12, week 18 and week 24

Completion date
03/12/2007

Eligibility

Key inclusion criteria
1. Mild to moderate Alzheimer's disease or vascular dementia; the diagnosis is based on the diagnostic criteria of NINCDS/ADRDA (McKhann et al. 1985) for probable Alzheimer’s disease, on the criteria of NINCDS/ADRDA and the relevant items of the criteria of NINDS-AIREN (Román et al. 1993) for possible Alzheimer's disease with cerebrovascular disease and on the criteria of NINDS-AIREN for probable vascular dementia
2. Presence of symptoms typical for dementia for at least 6 months
3. Neuropsychiatric Inventory (NPI): at least one item (other than delusions or hallucinations) ≥ 3 and total score ≥ 5

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
450

Key exclusion criteria
1. Ischaemic stroke with sequelae within the last three months or any type of haemorrhagic stroke within the last 12 months
2. Dementia of other origin or other neurological disorders

Date of first enrolment

26/04/2006

Date of final enrolment
22/05/2007

Locations

Countries of recruitment
Ukraine

Sponsor information

Organisation
Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany

Funder(s)

Funder type

Funder Name
Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		13/10/2025	25/11/2026	No	No