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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
[ ] 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 daily activities. Many people with dementia also experience psychological or behavioural symptoms such as anxiety, depression, irritability, agitation or loss of interest in activities. Researchers wanted to find out whether a special extract from the Ginkgo biloba plant, called EGb 761®, could safely improve thinking and memory abilities and help reduce these psychological and behavioural symptoms in people with dementia.

Who can participate?
Adults aged 50 to 100 years with mild to moderate Alzheimer's disease or vascular dementia could take part if they had experienced symptoms of dementia for at least 6 months and also had psychological or behavioural symptoms such as anxiety, depression, irritability or apathy.

What does the study involve?
Participants were randomly assigned to receive either a 240 mg tablet of EGb 761® or a placebo tablet once a day for 24 weeks. A placebo is a treatment that looks the same as the study medication but does not contain the active ingredient.
Neither the participants nor the study team knew which treatment each participant was receiving during the study. This was done to ensure that the results were assessed fairly.
Participants attended study visits during the 24-week treatment period. At these visits, researchers assessed memory, attention, thinking abilities and psychological or behavioural symptoms using standard questionnaires and tests. Participants also underwent safety assessments, including laboratory tests, physical and neurological examinations, monitoring of vital signs and heart activity recordings (ECGs). Any side effects or health problems that occurred during the study were recorded.

What are the possible benefits and risks of participating?
Participants receiving EGb 761® might have experienced improvements in memory, thinking

abilities or psychological and behavioural symptoms. However, these improvements could not be guaranteed, and participants might not have received any direct benefit from taking part. As with any medicine, there was a risk of side effects. Participants also had to attend study visits and complete assessments. Their health was monitored throughout the study to help identify and manage any problems that arose.

Where is the study run from?
The study was sponsored and coordinated by Dr. Willmar Schwabe GmbH & Co. KG in Karlsruhe, Germany. Participants were recruited from study centres in Belarus, Moldova and the Russian Federation.

When is the study starting and how long is it expected to run for?
Participant recruitment started in March 2008 and ended in October 2009. The study was completed in June 2010. Each participant took part in the study for 24 weeks.

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
523001.01.081

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-IT

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 21/04/2008, National Ethics Committee, Ministry of Health, Republic of Moldova (N. Testimitsanu street 27, Kishinev, 2020, Moldova; +373 222 05412; no email address available), ref: NECCM/167/21.04.2008

2. Approved 20/05/2008, Ethics Committee under the Federal Service on Surveillance in Healthcare and Social Development of Russian Federation (Slavyanskaya Sq. 4 bld 1, Moscow, 109074, Russian Federation; +7 6282319; no email address available), ref: EK-33848

3. Approved 04/12/2007, Ethic Committee, Public Health Institution (Semashko Street 8, Minsk, not available, Belarus; no telephone number provided; no email address available), ref: 0103-09 /8244

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 a validated computer program that linked random numbers to drug 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, 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
29/06/2010

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 for probable Alzheimer’s disease, on the criteria of NINCDS /ADRDA and the relevant items of the criteria of NINDS-AIREN 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 prior to screening
3. NPI at least one of the items “anxiety”, “apathy/indifference”, “irritability/lability” or “depression/dysphoria” rated ≥ 4 and total score ≥6

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
472

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
20/03/2008

Date of final enrolment
22/10/2009

Locations

Countries of recruitment
Belarus

Moldova

Russian Federation

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