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A study to assess the benefits and safety of a special extract manufactured from Ginkgo biloba (EGb 761) in people with dementia who also have psychological or behavioral 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, attention and daily functioning. Many people with dementia also experience psychological or behavioural symptoms such as anxiety, agitation, irritability or loss of interest. Researchers wanted to find out whether a special extract from the Ginkgo biloba plant, called EGb 761®, could help improve thinking and memory abilities and reduce behavioural and psychological symptoms in people with dementia. The study also assessed whether the treatment was safe and well tolerated.

Who can participate?
Adults aged 50 years and over with symptoms of dementia for at least 6 months could take part. Participants had to have Alzheimer's disease, Alzheimer's disease with cerebrovascular disease, or vascular dementia, together with psychological or behavioural symptoms.

What does the study involve?
Participants attended one of several study centres in Bulgaria and were randomly assigned to receive either EGb 761® tablets or placebo tablets, which looked the same but contained no active ingredient. Neither the participants nor the study team knew which treatment had been assigned until the study ended.
Participants took the study treatment twice daily for 22 weeks. During the study, their memory, attention and thinking abilities were assessed using standard tests. Behavioural and psychological symptoms were also evaluated. Safety checks included physical and neurological examinations, monitoring of vital signs, electrocardiograms (ECGs), 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 may have experienced improvements in memory, attention, thinking ability or behavioural symptoms, although this could not be guaranteed. Information gained from the study may help improve understanding of treatments for people with dementia in the future.

Possible risks included side effects from the study medication and any inconvenience associated with attending study visits, undergoing tests and taking part in medical examinations. Participants were monitored throughout the study to assess safety and identify any adverse effects.

Where is the study run from?
The study was sponsored by Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany, and was conducted at study centres in Bulgaria.

When is the study starting and how long is it expected to run for?
November 2003 to November 2006.

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)
Scientific, Principal investigator, Public

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Additional identifiers

Sponsor-ID
523001.01.061

Study information

Scientific Title
Randomised, double-blind, placebo-controlled, parallel-group, multicentre trial to confirm the efficacy, safety and tolerability of Ginkgo biloba special extract EGb 761 in patients suffering from Alzheimer’s Disease, vascular dementia or mixed type dementia with neuropsychiatric symptoms

Acronym
PLAGIN

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/12/2003, Specialized Commission for Permission of Conduct of Clinical Trials (Ministry of Healthcare, Sofia, -, Bulgaria; no telephone number provided; delovodstvo@mh.government.bg), ref: KU-75/04. 11. 03

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
Probable Alzheimer’s Disease, possible Alzheimer’s Disease with cerebrovascular disease or vascular dementia

Interventions
2 x 1 tablet 120mg EGb 761® or placebo oral for 22 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 score of the Syndrome Kurz-Test (SKT) battery compared to placebo. Primary outcome variable was the SKT test as an objective measure of cognitive impairment at baseline, week 12 and week 22

Key secondary outcome(s)
1. Safety measured using Laboratory tests at screening visit and week 22

2. Tolerability measured using adverse events at baseline, week 6, week 12, week 17 and week 22

Completion date
27/11/2006

Eligibility

Key inclusion criteria
1. Male or female outpatients, aged 50 years or older
2. Presence of symptoms typical for dementia for at least 6 months
3. Grade of cognitive impairment was between 9 – 23 points (both inclusive) in total score of SKT test battery at screening
4. Neuropsychiatric Inventory (NPI, 12 items) 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
449

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

Date of first enrolment
10/11/2003

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Bulgaria

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		03/04/2003	25/11/2026	No	No