ISRCTN10737194 https://doi.org/10.1186/ISRCTN10737194

A study to assess the benefits and safety of 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
27/11/2026

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 and behaviour. People with dementia may also experience psychological or behavioural problems such as anxiety, agitation, irritability or lack of interest. This study aimed to find out whether a special Ginkgo biloba extract (EGb 761®) is effective, safe and well tolerated in people with mild to moderate Alzheimer's disease, vascular dementia or mixed dementia who also have neuropsychiatric symptoms.

Who can participate?
Adults aged 50 to 100 years with mild to moderate Alzheimer's disease, vascular dementia or mixed dementia who had experienced symptoms of dementia for at least six months and met the study's assessment criteria for cognitive impairment and neuropsychiatric symptoms.

What does the study involve?
Participants were randomly assigned to receive either EGb 761® or a placebo tablet for 22 weeks. Neither the participants nor the study staff knew which treatment each participant received. Cognitive function was assessed at the start of the study and during follow-up. Safety was assessed using laboratory tests, and tolerability was assessed by recording adverse events throughout the study.

What are the possible benefits and risks of participating?
Participants may experience improvements in cognitive ability, memory, and health-related quality of life. However, the success of the treatment cannot be guaranteed. The study drug may cause mild adverse reactions, primarily gastrointestinal. Blood sampling may cause brief pain or bruising. Participants receiving a placebo will not receive the active study drug.

Where is the study run from?
Dr. Willmar Schwabe GmbH & Co. KG, Germany.

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

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

Who is the main contact?
Dr Robert Hoerr, robert.hoerr@schwabe.de

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Robert Hoerr

Contact details
Dr. Willmar Schwabe GmbH & Co. KG
Karlsruhe
Germany
76227
+49 721 4005492
robert.hoerr@schwabe.de

Additional identifiers

Sponsor-ID
523001.01.058

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
GINDEM-NP

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 27/05/2003, Ethics Commission of the State Pharmacological Centre, Ministry of Health of Ukraine (now operates as the State Expert Center of the Ministry of Health of Ukraine) (7 Hrushevskoho Street, Kiyev, 01021, Ukraine; +380 (044) 202-17-00; dec@dec.gov.ua), ref: 5.12-153/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
Mild to moderate Alzheimer's disease, vascular dementia or mixed type dementia

Interventions
2 x 1 tablet 120 mg 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 at baseline, week 12, week 22

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

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

Completion date
03/08/2006

Eligibility

Key inclusion criteria
1. Mild to moderate Alzheimer's disease, vascular dementia or mixed type dementia according to diagnostic criteria of NINCDS/ADRDA for probable Alzheimer’s disease, on the criteria of NINDS-AIREN for probable vascular dementia and on the relevant parts of both sets of criteria for possible Alzheimer's disease with cerebrovascular disease
2. Presence of symptoms typical for dementia for at least 6 months
3. SKT test battery total score of 9 – 23 (both inclusive) at screening
4. 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
487

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

Date of first enrolment
17/06/2003

Date of final enrolment
30/08/2004

Locations

Countries of recruitment
Ukraine

Sponsor information

Organisation
Dr Willmar Schwabe (Germany)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type

Funder Name
Dr. Willmar Schwabe

Alternative Name(s)
Dr. Willmar Schwabe GmbH & Co. KG, Dr. Willmar Schwabe GmbH, Schwabe Group, Schwabe

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available