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Pharmacodynamics/electroencephalographic (EEG) study with Ginkgo biloba special extract EGb 761®

Submission date	Recruitment status	[ ] Prospectively registered
21/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2011	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
523001.01.098

Study information

Scientific Title

An open-label, exploratory clinical trial to investigate the effects of Ginkgo biloba special extract EGb 761® on dopamine-induced executive cognitive functions and their neurophysiological correlation in subjects with mild cognitive deficits

Study objectives
Investigation of effects of EGb 761® on executive controlling functions and their correlation in electroencephalographic (EEG) examination in subjects with mild cognitive deficits

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of the University Hospital of Schleswig-Holstein, Campus Lübeck (Ethikkommission der Medizinischen Fakultät der Universitätsklinik Schleswig-Holstein, Campus Lübeck) approved on 19.01.2011, reference number: 10-236

Study design
Single-centre open-label single-arm exploratory clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild cognitive deficits

Interventions
Ginkgo biloba EGb 761® 240 mg film-coated tablets; 1 tablet/day for 8 weeks

EEG examinations; computer-based cognitive tests; psychological rating scales

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
1. Cognitive/clinical: error rate, error correction rate, error correction time, post-error slowing, post-non-inhibition slowing, stop signal reaction time in Flanker/Stop exercise; reaction time and electoral behaviour in recompensation exercise; cognitive test battery; Beck Depression Inventory II; FEDA
2. EEG: amplitude of error-related negativity (ERN), amplitude of error positivity, amplitude of

correction-related negativity, amplitude of N2 component, amplitude of Stop-ERN, amplitude of Stop-N2 in Flanker-Stop exercise; amplitude of feedback-related negativity (FRN) in the recompensation exercise

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Age 45 to 65 years
2. Informed consent according to legal requirements
3. Subject is capable to consent without any limitations
4. Existence of mild cognitive deficits, objectified by
4.1. A percentile below 16 in atleast 2 of 6 test parameters of the cognitive test battery
4.2. Alertness test (response time with/without audio warning)
4.3. Go/NoGo test (response time, mistakes)
4.4. Shared attention test (response time, mistakes) or
4.5 A percentile below 16 in one test parameter of the cognitive test battery and evidence of acquired attention disturbances and executive disturbances, relevant for every day life, i.e. questionnaire of experienced deficits of attention - distractibility and retardation in mental processes, FEDA-AV less than or equal to 45 or FEDA-EV less than or equal to 31 or fatigue and slowdown in practical activities, FEDA-AN less than or equal to 20

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Participation in another experimental drug trial at the same time or within the past 4 weeks before enrolment
2. Pregnancy or lactation period (exclusion by pregnancy test for all women of childbearing potential)
3. Women of child-bearing potential, i. e. who do not meet at least one of the following criteria:
3.1.Hormonal contraception for at least 6 months
3.2. Post menopausal status for at least 2 years
3.3. Hysterectomy
3.4. Bilateral oophorectomy
4. Active peptic ulcer disease or any gastrointestinal diseases with potential impairment of the

absorption of orally applied drugs (e.g. Billroth I + II, Crohn´s disease, ulcerative colitis, any kind of enterectomy), celiac disease, dietically inadequately controlled lactose intolerance, other diseases causing malabsorption or chronical diarrhoea)
5. Persisting or recurrent neurological or psychiatric disorder at the time of enrolment
6. Severe, medically uncontrolled cardiovascular or pulmonary disease
7. Clinically relevant renal or hepatic dysfunction (serum creatinine or serum ASAT, ALAT or Gamma GT above 3 times the upper limit of the reference range)
8. Other severe metabolic disorders or progressive diseases [e.g. insulin-dependent diabetes mellitus, anaemia, vitamin deficiencies, cancer, known human immunodeficiency virus (HIV) infection/Acquired immunodeficiency syndrome(AIDS), syphilis)
9. Abnormal neurological and/or psychopathological findings
10. Intake of prohibited medications
11. Total score in Mini-Mental-Status < 26
12. Status after apoplexia
13. Status after cranial or brain injury
14. Apraxia (i. e. Morbus Parkinson, Dystonia)
15. Severe and insufficiently corrected loss of vision or hearing, severe language difficulties or any other disability that may prevent the subject from co-operating adequately in the trial or that may interfere with neuropsychological test performance
16. Known hypersensitivity to Ginkgo biloba, Ginkgo biloba extract or any ingredient of the drug under study

Date of first enrolment
15/03/2011

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Schleswig-Holstein
Lübeck
Germany
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Sponsor information

Organisation
Dr. W. Schwabe GmbH & Co. KG (Germany)

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

Funder Name
Dr. W. Schwabe GmbH & Co. KG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration