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Effects of Ginkgo biloba extract EGb 761® on arteriosclerosis-relevant biomarkers in subjects with early stage metabolic syndrome

Submission date 23/11/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/01/2011	**Overall study status** Completed	
Last Edited 13/12/2013	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
523006.01.009

Study information

Scientific Title
An explorative clinical trial to investigate the effects of Ginkgo biloba extract EGb 761® on arteriosclerosis-relevant biomarkers in men and women with early stage metabolic syndrome

Study objectives
To evaluate the pharmacodynamic effects, safety and tolerability of a 6-month treatment with 120 mg twice daily Ginkgo biloba extract EGb 761® after a 1-month placebo run-in phase in subjects with early stage metabolic syndrome with regard to biochemical atherothrombotic risk markers and factors.

On 18/09/2012 the anticipated end date was changed from 31/12/2011 to 31/12/2013.

On 13/12/2013 the anticipated end date was changed from 31/12/2013 to 31/12/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee UMHAT "St. Ivan Rilski" EAD, 16/12/2010, ref: 38/16.12.2010

Study design
Phase I/IIA, single-centre, open trial with a within-subject comparison of diverse atherothrombotic risk markers

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a copy of subject information form

Health condition(s) or problem(s) studied
Early stage metabolic syndrome

Interventions
120 mg EGb 761® film coated tablets orally (p.o.) twice daily for 6 months after a one month single-blind run-in phase for eligibility assessment.

Intervention Type

Drug

Phase
Phase II/III

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

Primary outcome measure
1. Effects on diverse athero-thrombotic risk markers and factors after 6 months of investigational treatment (additionally selected biomarkers at screening, on baseline, after 1, 2, 4 and 6 months of investigational treatment)
2. Effects on mood state (Multidimensional Mood State Questionnaire [MDMQ] on baseline and after 2 and 6 months of investigational treatment)
3. Clinical safety and tolerability (adverse events, vital functions and clinical laboratory tests at each visit, ECG at screening, on baseline and after 6 months of investigational treatment)

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/01/2011

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Male and female Caucasian subjects; females are eligible for enrolment if non-pregnant, non-lactating, having a negative pregnancy test at VI-01 and VI-02+, post-menopausal or using medically adequate contraception
2. Aged 21 to 50 years (boundaries included)
3. Lipoprotein(a) fraction: Lp(a) greater than 25 mg/dL at VI-01 and VI-02
4. Early stage metabolic syndrome - at least two but not more than three of the criteria listed below at VI-01 and VI-02:
4.1. Waist circumference greater than or equal to 102 cm in men, greater than or equal to 88 cm in women
4.2. Morning fasting triglyceride levels greater than or equal to 150 mg/dL (1.70 mmol/L)
4.3. Morning fasting high density lipoprotein (HDL)-cholesterol less than 40 mg/dL (1.04 mmol/L) in men, less than 50 mg/dL (1.30 mmol/L) in women
4.4. Recumbent systolic blood pressure (SBP) greater than or equal to 130 mmHg or diastolic blood pressure (DBP) greater than 85 mmHg
4.5. Morning fasting glucose greater than or equal to 100 mg/dL (5.55 mmol/L)
5. Absence of confounding co-morbidity
6. Absence of confounding co-medication
7. Willing and able to provide informed consent
8. Willing and able to comply with all procedures of the trial and attend all scheduled visits at the investigational site

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Run-in-phase: 30 subjects; Active treatment phase: at least 24 subjects

Key exclusion criteria
1. Previous participation in the trial
2. Participation in another clinical trial with a registered or non-registered drug or food supplement within the last 3 months prior to entry into the present study
3. Evidence or suspicion of hypersensitivity to the investigational drug
4. History or presence of treatment demanding allergies (including drug allergies)
5. Presence of acute or chronic infection at the time of recruitment
6. Evidence or suspicion of any relevant congenital disease or abnormality
7. Evidence or suspicion of any relevant clinical abnormality (as based on medical history, physical examination, vital signs, and 12-lead electrocardiogram [ECG])
8. Known gastrointestinal disorders (e.g. gastro-oesophageal reflux, partial or total gastrectomy, enterectomy, inflammatory bowel disease, celiac disease, symptomatic lactose intolerance, other disorders associated with chronic diarrhoea) within the last 6 months prior to inclusion into the study
9. Limiting vital signs, in particular:
9.1. Resting recumbent heart rate less than 50 or greater than 90 bpm
9.2. ECG: QTc greater than or equal to 450 msec (acc. Fridericia), QRS greater than or equal to 100 msec, PQ greater than or equal to 200 msec
9.3. Subjects with cardiac pacemaker or implantable cardioverter defibrillator
10. Relevant adverse clinical laboratory finding except for those explained and/or compatible with early-stage metabolic syndrome, in particular (but not exclusively) haemoglobin less than 13 g/dl for men and less than 12 g/dl for women; liver enzymes greater than 1.5 the upper limit of the normal range
11. Positive results for hepatitis and human immunodeficiency virus (HIV) serology
12. Positive alcohol or drug test
13. Use of prohibited medications, in particular medications for the treatment of hypertension, coronary heart disease, cardiac insufficiency, dysrhythmia, diabetes, hyper- or dyslipidaemia, anti-coagulants; such medications should not have been used within the two months before visit 1 and during the trial
14. Use (within the last two months before visit 1) of prohibited food supplements that might confound to the study criteria
15. Donation of blood or plasma within the last 30 days before visit 1
16. Evidence or suspicion that the subject is (socially) drug dependent, including those drinking more than 40 g alcohol per day
17. Smoking more than 10 cigarettes per day
18. Adherence to a prohibited diet (e.g. vegetarian) or lifestyle (including extreme physical activities such as competitive sports and weight lifting)
19. Evidence or suspicion that the subject might not be willing or able to comply with the study directives and restrictions, or that the subject might not be sufficiently reliable and trustworthy
20. Subjects who are known or suspected not to be capable of understanding and evaluation the

information that is given to them as part of the obligatory information policy (informed consent), in particular regarding the risks and discomfort due to trial procedure to which they would agree to be exposed

Date of first enrolment
15/01/2011

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Bulgaria

Germany

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Industry

Website
http://www.schwabepharma.com/international/

ROR
https://ror.org/043rrkc78

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration