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# Safety, tolerability and pharmacokinetics of Ginkgo biloba special extract EGb 761® in patients with hepatic dysfunction

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| **Submission date**<br>02/10/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/11/2009 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>30/11/2009 | **Condition category**<br>Digestive System | [_] Individual participant data<br>[_] 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**
523001.01.092

## Study information

**Scientific Title**

Single-centre, open-label, parallel-group trial to study the in-vivo effects of impaired hepatic function on the safety, tolerability and pharmacokinetics of Ginkgo biloba special extract EGb 761® in man

## Acronym
EGb 761®: Impaired Hepatic Function

## Study objectives
To describe the pharmacokinetics, safety, and tolerability of single oral doses of EGb 761® in hepatic dysfunction relative to matched healthy controls.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee MHAT "St. Ivan Rilski" approved on the 25th August 2009 (ref: 16/25.08.2009)

## Primary study design
Interventional

## Study design
Single-centre controlled open-label parallel-group trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Liver cirrhosis

## Interventions
Period 1: a single oral dose 120 mg Ginkgo biloba special extract EGb 761®
Period 2: a single oral dose 240 mg Ginkgo biloba special extract EGb 761®

The first period is preceded by a screening visit for eligibility assessment within 21 to 2 days before hospitalisation. For each period, the subjects are hospitalised in the study clinic from the evening before dosing until 24.00 hours after dosing. Periods are at least one week apart for wash-out. An end-of-trial safety follow-up visit is scheduled within one week after Period 2.

## Intervention Type
Drug

## Phase
Phase I

## Drug/device/biological/vaccine name(s)
EGb 761®

## Primary outcome(s)
Clinical pharmacology criteria:
1. Pharmacokinetics: single-dose pharmacokinetics of relevant marker terpenes (Ginkgolide A,

Ginkgolide B and Bilobalide) in plasma (optional: in urine)
2. Wellbeing and adverse events
3. Recumbent resting blood pressure and pulse rate
4. Physical examination
5. Clinical laboratory safety tests

### Key secondary outcome(s)
No secondary outcome measures

### Completion date
28/02/2010

## Eligibility

### Key inclusion criteria
All subjects:
1. Males or females (females of non-child-bearing potential or of child-bearing potential while taking medically appropriate contraception)
2. Caucasian
3. Aged 21 to 60 years of age
4. Body mass index (BMI) between 18 - 30 kg/m^2
5. Body weight between 45 - 100 kg
6. Willing and able to provide informed consent

Healthy control subjects (CON):
7. Healthy based on the pre-study examination

Patients with moderate hepatic dysfunction (CTP-class B) (HEP):
8. Stable compensated liver cirrhosis (cryptogenic, post-hepatitis, alcohol-related) with histological or macroscopic (e.g. laparascopy, biopsy, ultrasound sonography or other adequate imaging techniques) confirmation
9. Child-Turcotte-Pugh (CTP) class B (sum of CTP-scores: 7 - 9)
10. Liver Vascular Index by Doppler ultrasonography T 12 cm/sec

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
21 Years

### Upper age limit
60 Years

### Sex

All

## Key exclusion criteria

General: all subjects -
1. Previous participation in the trial
2. Participant in any other trial during the last 90 days
3. Donation of blood during the last 60 days or a history of blood loss exceeding 300 ml within the last 3 months
4. History of any clinically relevant allergy (including hypersensitivity to the trial medications)
5. Presence of acute or chronic infection (HEP: other than related to the primary diagnosis - chronic hepatitis or chronic pancreatitis are no reason for exclusion)
6. Uncontrolled diabetes mellitus
7. Resting systolic blood pressure greater than 160 or less than 90 mmHg, diastolic blood pressure greater than 95 or less than 50 mmHg
8. Clinically relevant electrocardiogram (ECG)-abnormalities, prolonged QTc with greater than 450 msec in males and greater than 460 msec in females in particular
9. Positive human immunodeficiency virus (HIV) test
10. Positive alcohol or urine drug test on recruitment
11. Daily alcohol use of greater than 30 g alcohol
12. Smoking more than 10 cigarettes/day or equivalent of other tobacco products
13. Use of prohibited medication
14. Suspicion or evidence that the subject is not trustworthy and reliable
15. Suspicion or evidence that the subject is not able to make a free consent or to understand the information in this regard

General: all females -
16. Positive pregnancy test
17. Lactating
18. Not using appropriate contraception in premenopausal women

All healthy subjects:
19. Presence or history of any relevant co-morbidity
20. Presence of any clinically relevant abnormality in the laboratory safety tests, especially low haemoglobin, increased liver enzymes, increased serum creatinine
21. Positive serology for hepatitis B surface antigen (HBsAg), hepatitis B core antigen (anti-HBc) and hepatitis C virus antigen (anti-HCV)
22. History of alcohol and/or drug abuse

Patients with hepatic disease:
23. Biliary liver cirrhosis
24. Liver impairment due to space-occupying processes (e.g. carcinoma)
25. State after liver transplantation or patient scheduled for liver transplantation
26. Fluctuating or rapidly deteriorating hepatic function
27. Significant bleeding diathesis
28. Oesophageal bleeding within the last 8 weeks before study entry
29. More than moderate ascites on abdominal ultrasound (US)
30. Presence or history of any relevant co-morbidity other than hepatic disease
31. Clinically relevant abnormal laboratory values other than those associated or sufficiently explained by the existing liver disease, the cut-off level of serum haemoglobin for exclusion: 100 g/l
32. History of drug or alcohol abuse within 2 months prior to dosing

**Date of first enrolment**
01/11/2009

**Date of final enrolment**
28/02/2010

# Locations

**Countries of recruitment**
Bulgaria

**Study participating centre**
**Deptartment of Gastroenterology**
Sofia
Bulgaria
1431

# Sponsor information

**Organisation**
Dr. Willmar Schwabe GmbH & Co. KG (Germany)

**ROR**
https://ror.org/043rrkc78

# Funder(s)

**Funder type**
Industry

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration