ISRCTN32485300 https://doi.org/10.1186/ISRCTN32485300

Evaluation of the safety, tolerability and pharmacokinetics of repeated oral doses of Priaculin in healthy male volunteers

Submission date 06/05/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/06/2010	**Overall study status** Completed	
Last Edited 28/06/2010	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Fathi Abdul Malek

Contact details
Dr. Willmar Schwabe GmbH & Co. KG
Clinical Research Department
Willmar-Schwabe-Str. 4
Karlsruhe
Germany
76227

Additional identifiers

Protocol serial number
583001.01.103

Study information

Scientific Title

A randomised, placebo-controlled, double-blind phase I study to assess the safety, tolerability and pharmacokinetics of repeated p. o. doses of 75 to 600 mg Priaculin in healthy male volunteers

Study objectives
To investigate the safety, tolerability and pharmacokinetics of repeated once daily p. o. doses of 75 to 600 mg Priaculin in healthy male volunteers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 28/06/10:
Medical Research Council approved on the 14th of June 2010 (ref: 4697-1/2010-1017EKL)

Study design
Phase I single centre double blind randomised placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy male volunteers

Interventions
Priaculin film coated tablets (stepwise increasing doses from 75 mg to 150 mg to 300 mg for group 1 and from 300 mg to 450 mg to 600 mg for group 2) or placebo film coated tablets p. o. once daily for 22 days.
Group 2 starts after conclusion and data evaluation of group 1. During the treatment period the subjects are hospitalised in the study clinical unit from day -2 until day 24. The treatment period of each group is preceded by a screening visit for eligibility assessment. An end-of-trial safety follow-up visit is schedule within one week after day 24.

Intervention Type
Other

Phase
Phase I

Primary outcome(s)
Safety and tolerability
1. Wellbeing and adverse events checked daily
2. Cardiovascular safety checked daily
3. Clinical laboratory tests at screening, on day -1, 8, 15, 22 and within one week after the last clinical visit

Key secondary outcome(s))

1. Pharmacodynamic safety parameters
1.1. Blood pressure measured daily
1.2. Pulse rate measured daily
1.3. ECG performed at screening, on days -1, 1, 8, 15, 22 and within one week after the last clinical visit
2. Plasma pharmacokinetics assessed on day 1, 8, 15 and 22-24

Completion date
15/11/2010

Eligibility

Key inclusion criteria
1. Male
2. Caucasian
3. Age 30 - 55 years (included)
4. BMI between 18 and 26 kg/m2
5. Healthy on the basis of extensive pre-study investigation
6. Willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria
1. Previous participation in the present trial
2. Participation in any other trial during the last 90 days
3. Donation of blood or plasma within the last 90 days before recruitment
4. History of any clinically relevant allergy
5. Presence of acute or chronic infection
6. Subjects with history or present conditions of clinically relevant cardiovascular, urogenital, gastrointestinal, hepatic, metabolic, endocrine, neurological or psychiatric abnormalities, defined in the clinical trial protocol
7. Presence or history of regular/habitual diarrhoea or constipation
8. Resting supine systolic blood pressure (SBP) > 140 or < 100 mmHg, resting supine diastolic blood pressure (DBP) > 95 or < 60 mmHg
9. Resting pulse (PR) or electrocardiographic heart rate (HR) < 50 bpm or > 100 bpm
10. Drop in SBP upon one minute relaxed upright standing (orthostatic challenge) by > 25 mmHg, or symptoms of faintness or dizziness on standing irrespective of the extent of standing

blood pressure reduction
11. ECG-abnormalities: AV-block (AV-block grade I included), QT-interval >= 480 msec, QTc-interval (Bazett) >= 450 msec, sick-sinus syndrome
12. Subjects with relevant abnormalities in the clinical laboratory tests, defined in the clinical trial protocol
13. History of alcohol or (social) drug abuse
14. Positive alcohol or urine drug test
15. Daily consumption of > 30 g alcohol
16. Smoking more than 10 cigarettes/day or equivalent of other tobacco products or having done so within the last 6 months prior to inclusion into the study
17. Use of confounding medication
18. Suspicion or evidence that the subject is not reliable
19. Suspicion or evidence that the subject is not able to make a free consent or to understand the information detailed in the subject information sheet

Date of first enrolment
16/06/2010

Date of final enrolment
15/11/2010

Locations

Countries of recruitment
Germany

Hungary

Study participating centre
Dr. Willmar Schwabe GmbH & Co. KG
Karlsruhe
Germany
76227

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