

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	☒ Prospectively registered ☐ Protocol
Registration date 11/06/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 28/06/2010	Condition category Other	☐ Individual participant data ☐ 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

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)

Primary study design

Interventional

Study design

Phase I single centre double blind randomised placebo controlled trial

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 $\geq$ 480 msec, QTc-interval (Bazett) $\geq$ 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