

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

<b>Submission date</b> 06/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/06/2010	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

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 patient information sheet

## 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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

16/06/2010

## **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/m<sup>2</sup>
5. Healthy on the basis of extensive pre-study investigation
6. Willing and able to provide written informed consent

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Male

## **Target number of participants**

32

## **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)

## Sponsor details

c/o Dr. F. A. Malek  
Clinical Research Department  
Willmar-Schwabe-Str. 4  
Karlsruhe  
Germany  
76227

## 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

