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Bioequivalence of phenazopyridine HCl in healthy volunteers

Submission date	Recruitment status	[_] Prospectively registered
28/08/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/10/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2008	Urological and Genital Diseases	[_] 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
URG/STEROP/001

Study information

Scientific Title
Two-treatment, two-period, randomised, single-blind, cross-over bioequivalence of phenazopyridine HCl in 24 healthy volunteers

Study objectives

The present study aims at comparing the pharmacokinetics of the original formulation of phenazopyridine and a same generic product. This is necessary to demonstrate bioequivalence to regulatory authorities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IEC/IRB of the City Medical Committee, Karachi, Pakistan. Date of approval: 02/07/2008 (ref: ERB /HC/002)

Primary study design
Interventional

Study design
Randomised, single-blind, cross-over trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Local analgesic for the urinary tract

Interventions
To demonstrate the bioequivalence of a generic product containing phenazopyridine (one tablet x 100 mg) as test product Uropyrine® (Sterop Laboratories, Belgium) with the original formulation of phenazopyridine (one tablet x 100 mg) as reference product Pyridium® (Pfizer, USA). Both drugs will be administered orally in fasting state. All participants will be given each of the two drugs only once, in a cross-over design. The duration of washout period is 7 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Phenazopyridine HCl

Primary outcome(s)
To determine the bioequivalence of both formulations of phenazopyridine, as determined by the following (monitored for 24 hours after administration of drug):
1. Measurement of the pharmacokinetic parameters
2. Maximum serum concentration (Cmax)
3. Time to maximum serum concentration (tmax)
4. Area under the curve (AUC)

Key secondary outcome(s)
Side effects of each of the two product regimens, monitored at 4, 10 and 24 hours. Follow up will be carried out after 7 days.

Completion date
04/11/2008

Eligibility

Key inclusion criteria
1. Healthy subjects aged 18 to 55 (male and female)
2. Physically and mentally healthy subjects as confirmed by an interview, medical history, clinical examination, laboratory tests
3. Informed consent signed by the subject
4. The subject is co-operative and available for the entire study
5. Not pregnant or nursing
6. Normal renal and hepatic function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Evidence in the subject medical history or in the medical examination of any clinically significant hepatic, renal, gastrointestinal, cardiovascular, pulmonary, haematological or other significant acute or chronic abnormalities which might influence either the safety of the subject or the absorption, distribution, metabolism or excretion of the active agent under investigation
2. Hypersensitivity to subject drug, atopic eczema or allergic bronchial asthma
3. Evidence of hypertension (blood pressure after 3 minutes sitting >160/95 mmHg)
4. Evidence of chronic or acute infectious diseases
5. History or evidence of malignant tumours
6. Evidence of hyperuricaemia, elevated serum uric acid (>8.0 mg/dl)
7. Hepatic or renal impairment; elevated serum creatinine (>1.4 mg/dl)
8. Planned vaccination during the time course of the study
9. Adherence to a diet (e.g., vegetarian) or life style (including extreme sports) that might interfere with the investigation
10. Laboratory test results outside the tolerance values as laid down by the study centre, which may be an evidence of disease. Positive result of HIV1/2, Hepatitis C virus (HCV) antibody or Hepatitis B (HBs) antigen testing
11. Regular use of any medication within four weeks prior to commencement of the study (self-medication or prescription)
12. Single use of any medication (including over-the-counter medication) that are not expressively permitted within two weeks prior to start of the study

13. Abuse of alcohol, caffeine or tobacco (equivalent to more than 10 cigarettes a day)
14. Drug addiction
15. Participation in a clinical investigation or blood donation of more than 250 ml within the past eight weeks or blood donation of less than 250 ml within the past 4 weeks
16. Subjects who are known or suspected:
16.1. not to comply with the study directives
16.2. not to be reliable or trustworthy
16.3. not to be capable of understanding and evaluating the information given to them as part of the formal information policy (informed consent),in particular regarding the risks and discomfort to which they would agree to be exposed
16.4. to be in such a precarious financial situation that they no longer weigh up the possible risks of their participation and the unpleasantness they may be involved in

Date of first enrolment
04/08/2008

Date of final enrolment
04/11/2008

Locations

Countries of recruitment
Pakistan

Study participating centre
Office of the Principal
Karachi
Pakistan
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Sponsor information

Organisation
Phoenix International (UAE)

Funder(s)

Funder type
Not defined

Funder Name
Phoenix International (UAE)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration