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Bioequivalence of olmesartan medoxomil versus hydrochlorothiazide in Korean subjects

Submission date	Recruitment status	[_] Prospectively registered
06/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2014	Other	

Plain English summary of protocol

Background and study aims:
This study tests the effect of two drugs, Olmetec Plus and Olmesartan in healthy Korean subjects.

Who can participate?
Healthy Korean volunteers, aged between 19 and 55 years.

What does the study involve?
Participants will be randomly allocated to one of two groups: A or B. During the first period, participants from group A will receive a reference drug (Olmetec Plus®) while participants from group B will receive a test drug (Oldesar Plus). After one week, the order will be reversed.

What are the possible benefits and risks of participating?
There is no direct benefit from participation in the study. Information learned from the study may help other people in the future. Participants may experience side effects related to the study drug, but this will be monitored carefully for any negative effects. Participants may experience discomfort during blood sampling, include faintness, swelling or bruising at the site from where blood is drawn.

Where is the study run from?
Clinical Trial Center, Seoul, Korea

When is study starting and how long is it expected to run for?
The study started in June 2010 and ran until 2011.

Who is funding the study?
Pacific Pharma Corporation, Seoul, Korea

Who is the main contact?
Dr. Min-Gul Kim
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BIBE2010-23

Study information

Scientific Title
Pharmacokinetic properties and bioequivalence of olmesartan medoxomil versus ydrochlorothiazide in Korean subjects

Study objectives
The present study aims at comparing the pharmacokinetics of the original formulation of Olmesartan medoxomil / Hydrochlorothiazide and a same generic product. This is necessary to demonstrate bioequivalence to regulatory authorities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chonbuk National University Hospital Institutional Review Board, Jeonju, Republic of Korea, 28 June 2010, ref: CBBEIRB10-06-07

Study design
Open label randomised 2-treatment 2-period 2-sequence crossover design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Healthy Subjects

Interventions
To demonstrate the bioequivalence of a generic product containing phenazopyridine (one tablet x 100 mg) as test product Uropyrine® with the original formulation of phenazopyridine (one tablet x 100 mg) as reference product Pyridium®.
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
Other

Phase
Not Specified

Primary outcome measure
Measurement of the pharmacokinetic parameters:
1. Serum Cmax
2. AUC

Secondary outcome measures
Measurement of the pharmacokinetic parameters - Serum Tmax

Overall study start date
08/07/2008

Completion date
17/07/2008

Eligibility

Key inclusion criteria
1. Healthy subjects aged 19 to 55
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. Not pregnant female subject

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Use of any drugs known to significantly induce or inhibit drug-metabolizing enzymes within 1 month prior to dosing
2. Use of prescription or nonprescription drugs within 10 days prior to the first dose of study medication
3. Subjects who are known or suspected not to comply with the study directives
4. Participating in a bioequivalence study or other clinical study within 3 month preceding the first dose of study medication
5. Pregnant or nursing females
6. Subject who are hypersensitive to study medication or other related compounds
7. History of sensitivity to thiazide diuretics or sulfonamides
8. Acute or Chronic renal failure (creatinine clearance < 30mL/min), anuric patient
9. Severe Hepatic failure
10. Biliary atresia, biliary cirrhosis
11. Hyponatremia, hypokalemia, hypercalcemia, hyperuricemia patient
12. Addison's disease patient
13. Galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption

Date of first enrolment
08/07/2008

Date of final enrolment
17/07/2008

Locations

Countries of recruitment
Korea, South

Study participating centre

20, Geonji-ro
Jeonju
Korea, South
561-172

Sponsor information

Organisation
Pacific Pharma Corporation (Korea, South)

Sponsor details
710, Eonju-ro
Gangnam-Gu
Seoul
Korea, South
135-733

Sponsor type
Industry

Website
http://www.pacificpharm.co.kr/

Funder(s)

Funder type
Industry

Funder Name
Pacific Pharma Corporation (Korea, South)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No