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The bioavailability of itopride hydrochloride extended release versus itopride hydrochloride immediate release

Submission date 03/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 03/11/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/11/2009	**Condition category** Digestive System	[_] 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
KORE-08-02

Study information

Scientific Title

A comparison of bioavailability of itopride hydrochloride extended release (once daily) with that of itopride hydrochloride immediate release (three times daily): a randomised, open-label, three treatment, three sequence crossover study

Study objectives
The objective of this study is to assess the bioavailability of a test formulation of itopride hydrochloride 150 mg extended release (ER) tablets (once daily for 4 days) given under fasting and fed conditions relative to itopride hydrochloride 50 mg immediate release (IR) tablets given three times daily for 4 days, in healthy human adult male subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Seoul National University College of Medicine/Seoul National University Hospital Institutional Review Board approved on the 25th February 2009

Study design
Randomised open-label three-sequence three-period single centre crossover study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Gastrointestinal motility

Interventions
1. Study drug: itopride HCl, 150 mg, 3 times a day for 6 days, per oral
2. Comparator: itopride HCl, 50 mg, 3 times a day for 6 days, per oral
Total duration of treatment: 21 days (7 days per each regimen)

Regimen A: Administration of itopride HCl 150 mg ER tablet every 24 hours under fasting conditions for 4 days (test)
Regimen B: Administration of itopride HCl 150 mg ER tablet every 24 hours under fed condition for 4 days (test)
Regimen C: Administration of itopride HCl 50 mg IR tablet administration for 4 days, 30 minutes before meals (reference). Meals will be provided at approximately 9am, 2pm and 7pm.

Total duration of follow-up: 30 days (window period: +6 days)

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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Itopride hydrochloride

Primary outcome(s)
Assess the rate and extent of absorption of itopride from itopride ER tablets under fasting and fed conditions compared to that of itopride IR tablets based on pharmacokinetic parameters. Timepoint: study day 4 of each period.

Key secondary outcome(s))
Observe the safety of the formulations based on clinical and laboratory examinations during the study. Timepoint: at screening day, day -1 of study period 2, day 5 of study period 3.

Completion date
10/07/2009

Eligibility

Key inclusion criteria
1. Korean males aged between 22 and 55 years, inclusive (at time of informed consent)
2. Body mass index (BMI) 18 to 27 kg/m^2, inclusive. BMI is calculated as weight (kg) divided by the square of height (m).
3. A condition of general good health, based upon the results of a medical history, physical examination, vital signs, laboratory profile, and a 12-lead electrocardiogram (ECG)
4. Subjects who have given their written informed consent prior to participation in the study
5. Availability of subject for the entire study period, ability to understand and communicate with the investigators and staff, and willingness to adhere to protocol requirements including all the restrictions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Male

Key exclusion criteria
1. History or clinical evidence of significant respiratory, cardiovascular, pulmonary, hepatic, renal, hematological, gastrointestinal, endocrine, immunologic, dermatological, musculoskeletal, neurological or psychiatric disease
2. Alcohol dependence, alcohol abuse or drug abuse within the past one year
3. Moderate to heavy smoking (greater than 10 cigarettes/day)
4. Body weight is less than 50 kg
5. Subject who had clinically significant illness within 4 weeks before the start of the study
6. Present or previous significant drug allergy to any prescription or over-the-counter medication
7. Subjects who test positive in serological tests and drug tests (serological tests for hepatitis B surface [HBs] antigen, hepatitis C virus [HCV] antibody, and human immunodeficiency virus [HIV] antibody, and screening for drug abuse)
8. Any history of hypersensitivity to itopride and contraindications like gastrointestinal haemorrhage, mechanical obstruction or perforation
9. Subjects with active or a history of peptic ulceration
10. Subjects with any other clinical condition, which might affect the absorption, distribution, biotransformation or excretion of the study drug
11. Subject who has participated in any other clinical trial involving drug administration and collection of blood samples or has donated blood (or had bled more than 400 ml) in the preceding 12 weeks period of the study
12. Any prescription drug, over-the-counter medication, or herbal medications within 14 days prior to scheduled study drug administration
13. Consumption of alcohol within the 1-day period prior to study drug administration
14. Subjects who show the following vital signs results
14.1. Systolic blood pressure less than or equal to 90 mmHg or greater than or equal to 150 mmHg
14.2. Diastolic blood pressure less than or equal to 60 mmHg or greater than or equal to 100 mmHg
15. Subjects who have pulse rate below 50/minute or above 100/minute
16. Previous enrolment in this study
17. Otherwise judged by the investigator to be inappropriate for inclusion in the study

Date of first enrolment
10/03/2009

Date of final enrolment
10/07/2009

Locations

Countries of recruitment
Korea, South

Study participating centre
Abbott Korea Limited
Seoul
Korea, South
135-735

Sponsor information

Organisation
Abbott Korea Limited (South Korea)

ROR
https://ror.org/053evkn98

Funder(s)

Funder type
Industry

Funder Name
Abbott Korea Limited (South Korea)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration