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Study Investigating the Pharmacokinetic Interaction Between INX-08189 and Verapamil HCL ER in Healthy Volunteers (INX-189-005)

This study has been completed.

Sponsor:
Bristol-Myers Squibb

Information provided by (Responsible Party):
Bristol-Myers Squibb

ClinicalTrials.gov Identifier:
NCT01471704

First received: November 3, 2011
Last updated: June 21, 2012
Last verified: June 2012
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to evaluate the potential for a pharmacokinetic (PK) drug-drug **interaction** between INX-08189 and extended release verapamil hydrochloride (verapamil HCL ER).

Condition	Intervention	Phase
Healthy	Drug: INX-08189 50 mg Drug: 240 mg verapamil HCL ER Drug: 50 mg dose of INX-08189 and 240 mg verapamil HCL ER	Phase 1 **Phase 2**

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Pharmacokinetics Study
Intervention Model: Crossover Assignment
Masking: Open Label
Primary Purpose: Health Services Research

Official Title: A Phase 1b, Drug-Drug **Interaction** Study Investigating the Pharmacokinetic **Interaction** Between INX-08189 and Verapamil HCL ER in **Healthy** Volunteers

Resource links provided by NLM:

MedlinePlus related topics: Drug Reactions

Drug Information available for: Verapamil hydrochloride

U.S. FDA Resources

Further study details as provided by Bristol-Myers Squibb:

Primary Outcome Measures:

- Effect of multiple doses of verapamil HCL ER 240 mg on the PK profile of INX-08189, and the effect of a single dose of INX-08189 on the PK profile of verapamil. [Time Frame: INX-08189 and Verapamil: Study Day 0 (INX-08189), Study Day 12 (Verapamil) and subsequently at 30 minutes, and 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24 hours after dosing. INX-08189 also at 48, 72, and 96 hours after initial dose.]
  [Designated as safety issue: Yes]

  PK for INX-08189 and verapamil by: maximum plasma concentration (Cmax), time Cmax is observed (Tmax), plasma concentration at end of dosing (Ctau), area under plasma concentration-time curve; time 0 to last measurable plasma concentration (AUC0-last), area under plasma concentration-time curve; time 0 to infinity (AUC0-inf), area under plasma concentration-time curve; 0 to end of dosing (AUC0-tau), elimination half-life (t1/2), apparent oral clearance (CL/F), and apparent oral volume of distribution (Vz/F).

- Safety of a single dose of INX-08189 50 mg alone & combined with verapamil HCL ER 240 mg after subjects received verapamil HCL ER QD for 6 days [Time Frame: Study Day -1, during the 24-hours post-dose, Study Day 2 to 4, 5, 6, 7 to 11, 12, and 13 to 16]
  [Designated as safety issue: Yes]

  Safety and tolerability parameters, including adverse event, concurrent medication, clinical laboratory, electrocardiogram (ECG) and vital signs assessments

Enrollment: 24
Study Start Date: October 2011
Study Completion Date: November 2011
Primary Completion Date: November 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: INX-08189 50 mg Study Day 0: Single 50 mg dose of INX-08189 in the morning	Drug: INX-08189 50 mg Study Day 0: Single 50 mg dose of INX-08189 in the morning
Active Comparator: 240 mg verapamil HCL ER Study Days 6 to 11: 240 mg verapamil HCL ER once daily (QD) in the morning	Drug: 240 mg verapamil HCL ER Study Days 6 to 11: 240 mg verapamil HCL ER once daily (QD) in the morning
Active Comparator: INX-08189 50 mg & verapamil HCLER 240 mg Study Day 12: Co-administration of single 50 mg dose of INX-08189 and 240 mg verapamil HCL ER in the morning	Drug: 50 mg dose of INX-08189 and 240 mg verapamil HCL ER Study Day 12: Co-administration of single 50 mg dose of INX-08189 and 240 mg verapamil HCL ER in the morning

Detailed Description:

This is a single-center, open-label, single-sequence, crossover, drug-drug interaction study in healthy subjects.

Primary Objectives:

Safety

- To evaluate the safety of a single dose of INX-08189 (50 mg) alone and combined with verapamil HCL ER (240 mg) after subjects receive verapamil HCL ER QD for 6 days

Pharmacokinetic

- To evaluate the effect of multiple doses of verapamil HCL ER (240 mg) on the pharmacokinetic (PK) profile of INX-08189 and the metabolite INX-08032, and the effect of a single dose of INX-08189 on the PK profile of verapamil and the metabolite norverapamil

Eligibility

Ages Eligible for Study: 18 Years to 55 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

Subjects must meet the following criteria at the screening visit (Visit1) and Visit 2 in order to be eligible for study drug administration:

1. Must be a healthy male or female between 18 and 55 years of age (inclusive) with body mass index (BMI) between 18 and 30 kg/m2 (inclusive), and weigh > 50 kg at the time of signing the informed consent;
2. Capable of giving written informed consent that includes compliance with the requirements and restrictions listed in the consent form. Signed informed consent must be on file prior to screening procedures;
3. Subject is able to understand and comply with the protocol requirements, instructions and restrictions;
4. Must be a non-tobacco user for at least 3 months prior to selection;
5. Healthy on the basis of physical examination, medical history, vital signs, electrocardiogram and clinical laboratory tests at screening;
6. Women must be postmenopausal for at least 2 years or be surgically sterile with complete hysterectomy or bilateral oophorectomy, and not be pregnant nor be breastfeeding;
7. Male subjects, who are not surgically sterile with vasectomy, must agree to use a double barrier method of birth control, such as, a condom plus spermicidal agent (foam/gel/film/cream/suppository). This criterion must be followed from the time of the first dose of study medication until 30 days after the last dose of medication. Male subjects cannot donate sperm during the study and for 3 months after receiving the last dose of the study drug.

Exclusion Criteria:

Subjects must NOT meet the following criteria at the Screening Visit (Visit1), in order to be eligible for study drug administration at Visit 2:

1. Infection with Hepatitis A, B or C Virus;

2. Infection with the Human Immunodeficiency Virus (HIV);
3. History of or any current medical condition which could impact the safety of the participant in the study;
4. Current active or underlying GI, cardiovascular, neurologic, psychiatric, metabolic, renal, hepatic, respiratory, inflammatory, or infectious disease;
5. Clinically significant abnormalities on centrally read ECG including evidence of bradycardia (rate < 60 bpm) or evidence of PR prolongation;
6. Screening vital signs representing a heart rate of < 60 bpm, systolic blood pressure < 90 mm Hg, and diastolic blood pressure < 60 mm Hg;
7. Currently significant diarrhea, gastric stasis, or constipation that in the investigator's opinion could influence drug absorption or bioavailability;
8. Safety laboratory abnormalities at screening which are clinically significant, or absolute neutrophil count of < 1800 cells/mm3, or platelet count < 130,000 cells/mm3, or hemoglobin < 12 g/dl for women and < 13 g/dl for men;
9. Women of child bearing potential, pregnant or breastfeeding;
10. Current abuse of alcohol or illicit drugs, or history of alcohol or illicit drug abuse within the preceding 2 years;
11. A positive urine drug test at screening;
12. Consumption of more than 2 units of alcoholic beverages per day or more than 14 units per week (1 unit of alcohol equals 1 glass of beer, 1 glass of wine, 25ml shot of 40% spirit), consumption of alcohol 72 hours before or after study medication intake, consumption of an average of more than five (5) 240 ml servings of coffee or other caffeinated beverages per day;
13. Use of chronic prescription medications within 3 months, acute prescription medications within 14 days, or systemic over-the-counter (OTC) medications, including vitamins, within 7 days of starting the study;
14. Received an investigational drug or vaccine or used an investigational medical device within 3 months or 5 half lives (whichever is longer) before the planned start of treatment or having participated previously in a study with INX-08189;
15. Subjects who have used any drugs or substances known to inhibit or induce cytochrome (CYP) P450 enzymes and/or P-glycoprotein (P-gp) within 28 days prior to the first dose and throughout the study;
16. Consumption of grapefruit or grapefruit juice starting 48 hours before Study Day -1, during the subject's confinement in the unit, and during the outpatient follow-up periods.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01471704

Locations

United States, Minnesota

Prism Research, LLC
St Paul, Minnesota, United States, 55114

Sponsors and Collaborators

Bristol-Myers Squibb

Investigators

Study Director: Ralph Campaneria, MD

More Information

No publications provided

Responsible Party:	Bristol-Myers Squibb
ClinicalTrials.gov Identifier:	NCT01471704 History of Changes
Other Study ID Numbers:	AI472-005, INH-189-005
Study First Received:	November 3, 2011
Last Updated:	June 21, 2012
Health Authority:	United States: Food and Drug Administration

Keywords provided by Bristol-Myers Squibb:
Pharmacokinetics
PK
INX08189
Verapamil
Inhibitex

Additional relevant MeSH terms:

Verapamil
Anti-Arrhythmia Agents
Calcium Channel Blockers
Cardiovascular Agents
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Therapeutic Uses
Vasodilator Agents

ClinicalTrials.gov processed this record on January 04, 2016