

A Phase 1, Open-Label, Four-Period, Two-Sequence, Two-Treatment, Single Dose, Randomized, Crossover Bioequivalence Study of a Test Tablet Formulation of Ravidasvir with the Reference Tablet Formulation of Ravidasvir in Healthy Adult Volunteers Under Fasting Conditions

ACTRN12620000037909

Status	COMPLETED
Phase	Phase 1
Sponsor	Drug for Neglected Diseases initiative
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (14)

- Have the ability to understand and sign a written informed consent form, which must be obtained prior to initiation of study procedures.
- Must be between 18 and 55 years of age, inclusive, at the date of ICF signature
- Must be a non-smoker or an ex-smoker for more than 90 days. The use of nicotine or nicotine-containing products or electronic cigarettes must be discontinued 90 days prior to the first admission day of the study.
- Must have a calculated body mass index (BMI) of 18.0 to 29.9 kg/m².
- Must be HIV-1 antibody negative.

... and 9 more (see full listing online)

Exclusion (15)

- Healthy volunteers with any hematologic or urinary analyte that is outside the normal limits of the study laboratory and have been determined by the Investigator to have clinical significance at Screening will be excluded
- Pregnant or lactating female healthy volunteers.
- Female healthy volunteers who utilize hormonal contraceptive as one of their birth control methods.
- Have any serious past or active medical condition or psychiatric illness which, in the opinion of the Investigator, would interfere with subject treatment, assessment, or compliance with the protocol. This would include renal, cardiac, hematologic, hepatic, pulmonary (including chronic asthma), endocrine (e.g., diabetes), central or peripheral nervous, gastrointestinal (including an ulcer), vascular, metabolic (thyroid disorders, adrenal disease), surgery (e.g stomach bypass) or immunodeficiency disorders, active infection, or malignancy that is clinically significant or requiring treatment.
- Have participated in an investigational trial involving administration of any investigational compound within 90 days prior to the study dosing or 5-times the half-life of the drug tested in the previous clinical trial, whichever is longer (time calculated relative to the last dose in the previous clinical trial).

... and 10 more (see full listing online)

Locations (1 total)

Kuala Lumpur, Malaysia