A Two-Part Study to Assess the Effects of Ritonavir on PRN1008 Pharmacokinetics, and the Effect of PRN1008 on QTc Interval Compared to Placebo and Moxifloxacin in Healthy Participants

ACTRN12618001036202

Status	RECRUITING
Sponsor	Principia Biopharma, Inc.
Enrollment	40 participants

Plain Language Summary

PRN1008 is an experimental drug being developed to treat certain immune-related conditions, and this study is investigating two specific questions about its safety profile. The first part looks at whether taking PRN1008 together with ritonavir (a drug commonly used to boost levels of other medications in the blood) changes how much PRN1008 gets into the bloodstream. The second part tests whether PRN1008 at therapeutic and higher-than-therapeutic doses affects the heart's electrical rhythm — specifically the QT interval, which when prolonged can cause dangerous heart arrhythmias.

This is a study in healthy participants (not people with any specific disease), and is a standard step in the development of any new drug before it is tested in larger patient populations. Both parts of the study involve carefully monitored dosing periods with frequent blood tests and heart monitoring.

You may be eligible if you are a healthy adult aged 18–55, have a BMI between 18 and 30, are not on any prescription or over-the-counter medications, do not smoke more than two tobacco products per month, and have no history of heart rhythm problems. People with HIV, hepatitis, significant drug allergies, or a family history of sudden cardiac death are not eligible.

Key Eligibility Criteria

Inclusion (5)

- Healthy adult male or non-pregnant, non-lactating females, 18 to 55 years of age (inclusive) at the time of screening
- Body mass index (BMI) greater than or equal to 18 and less than or equal to 30 (kg/m2) (inclusive) and a minimum body weight of 45 kg
- Able to participate and comply with all study procedures and restrictions, and willing to provide written informed consent to participate in the study
- A female subject of childbearing potential with a negative pregnancy test must agree for the duration of active treatment to use an effective means of contraception (hormonal contraception methods that inhibits ovulation, intrauterine device, intrauterine hormone-releasing system, bilateral tubal ligation, vasectomized partner, condoms or sexual abstinence). Unless surgically sterile, postmenopausal females should have menopause confirmed by FSH testing.
- Negative urine drug and alcohol breath testing at screening and at each period check-in (Day -1). Screening drug/alcohol testing may be repeated once if deemed appropriate by the site Investigator

Exclusion (21)

- Use of any prescription or over-the-counter (OTC) medications, including herbal products and supplements, within the 14 days prior to Day -1 or 5 half-lives, whichever is longer. Use of hormonal contraception and less than or equal to 2 g paracetamol per day is allowed prior to and during the study.
- Positive testing for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or hepatitis C antibodies (HCV)
- Use of more than two tobacco/nicotine-containing products per month within 6 months prior to the first study drug administration
- History or presence of alcoholism or drug abuse within the 2 years prior to the first study drug administration

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618001036202

• Regular alcohol consumption greater than 14 units per week (1 unit equals ½ pint beer, 25 mL of 40 percent spirit, or a 125 mL glass of wine)

... and 16 more (see full listing online)

Locations (1 total)

Nucleus Network - Melbourne, VIC, Australia