First-time-in-human Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RB201 in Healthy Adult Subjects

ACTRN12625000694415

Status	RECRUITING
Phase	Phase 1
Sponsor	Rarefied Biosciences Australia PTY LTD
Enrollment	88 participants

Plain Language Summary

The immune system is a finely balanced system, and in autoimmune diseases, it mistakenly attacks the body's own healthy tissues. RB201 is a new oral drug being tested for the first time in humans, designed to regulate the immune system in a way that could reduce the damaging inflammation seen in autoimmune conditions. Researchers do not yet know the best dose, so this study will carefully test escalating amounts of the drug, starting low and increasing cautiously.

Participants will either receive RB201 or a placebo (dummy pill), and will stay at the study facility for monitoring during the dosing period. Blood tests will track how the drug behaves in the body and how it affects immune cell levels.

This study is open to healthy adults aged 18 to 60 in good general health, with a weight between 40 and 120 kg. Participants must not have a history of significant illness, active infections, autoimmune disease, cancer, tuberculosis, or HIV/hepatitis. Women who are pregnant or breastfeeding are not eligible.

Key Eligibility Criteria

Inclusion (10)

- Is male or female, age 18 to 60 years, inclusive, at Screening.
- Weight at Screening of greater than or equal to 40 kg and less than or equal to 120 kg
- In good general health, determined by no clinically significant findings in the opinion of the Investigator from medical history, physical examination, 12-lead electrocardiogram (ECG), clinical laboratory findings, and vital signs at Screening and Check-in.
- Hemoglobin, hematocrit, white blood cell count, absolute neutrophil count, absolute lymphocyte count, platelet count, ALT and AST results all not clinically significant as per the Investigator at the Screening Visit. Tests may be repeated at the discretion of the Investigator to confirm abnormalities.
- Creatinine clearance based on the Cockcroft-Gault equation of greater than or equal to 80 mL/min.

... and 5 more (see full listing online)

Exclusion (16)

- Any clinically significant underlying illness in the opinion of the Investigator.
- Any history or sign of significant chronic active or recurrent infection, or screening laboratory evidence consistent with a significant chronic active or recurrent infection requiring treatment with antibacterials, antivirals, or antifungals.
- Treatment of any infection with IV (within 30 days of Screening) or oral (within 14 days of Screening) antibacterials, antivirals, or antifungals.
- History of clinically significant hematologic or bone marrow disease or blood dyscrasias.
- History of latent tuberculosis that was not adequately treated as per guidelines

... and 11 more (see full listing online)

Locations (1 total)

NSW, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000694415

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000694415