A Single-Center, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalating Study to Evaluate the Safety and Tolerability of KDF-07002 in Healthy, Adult Volunteers

ACTRN12609000086268

Status	RECRUITING
Phase	Phase 1
Sponsor	Nucleus Network, Ltd.
Enrollment	54 participants

Plain Language Summary

This is an early-stage (Phase 1) safety study testing a new investigational drug called KDF-07002 in healthy adult male volunteers. The purpose is to find out how safe and well-tolerated the drug is when given as a single intravenous (into a vein) dose, and to understand how the body processes it. Different groups of participants will each receive a progressively higher dose. Safety will be monitored closely for 7 days after the dose.

You may be eligible if:
- You are a male between 18 and 60 years old
- You are in good general health with no significant medical conditions
- You have easy-to-access veins for blood draws and injections
- You agree to use reliable contraception if sexually active during the study and for 30 days after

You may NOT be eligible if:
- You have a known sensitivity to imaging contrast agents
- You use illicit drugs or are alcohol-dependent
- You have participated in another drug study in the past 30 days
- You have donated blood in the past 30 days or had major surgery or injury in the past 45 days
- You have epilepsy, seizures, anaemia, asthma, COPD, liver or kidney disease, or a bleeding disorder
- You have had your spleen removed or have a history of pancreatitis
- You take warfarin (a blood thinner)
- You have an allergy to eggs

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (5)

- Be a male between the ages of 18 and 60 years, inclusive.
- Be healthy and have an acceptable medical history (defined as individuals who in the view of the investigator are free from significant cardiac, pulmonary, gastrointestinal, hepatic, renal, hematological, neurological, infective, or psychiatric diseases and confirmed by medical history, physical examination, and laboratory tests).
- Have readily accessible peripheral venous access sites for administration of clinical trial material and blood sampling.
- Subjects who are sexually active must also agree to a reliable form of contraception during the study and for 30 days following administration of the study drug.
- Have the ability to understand the requirements of the study, be willing to provide written informed consent as evidenced by signature on an informed consent document approved by the institution's Human Research Ethics Committee (HREC), and agree to abide by the study restrictions

Exclusion (21)

• Have a known sensitivity to any imaging contrast agents
• Be an intravenous drug user, user of any illicit drugs, or dependent on alcohol
• Have participated in an investigational drug or device study within the past 30 days
• Have donated blood or blood products within the past 30 days prior to pretreatment baseline
• period.
... and 16 more (see full listing online)

Locations (1 total)

Australia