Multiple Ascending Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetics of KSHN001034 in Healthy Postmenopausal Female Volunteers

NCT06995482

Status	RECRUITING
Phase	Phase 1
Sponsor	Kashiv BioSciences, LLC
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (8)

- Able to provide written Informed Consent and communicate with the investigator and comprehend study-related procedures.
- Healthy, postmenopausal females aged 45 to 60 years old (inclusive), as determined by medical history and physical examination.
- Body Mass Index at screening between 18 and 30 kg/m2, inclusive.
- Post-menopausal females (Menopause is defined as the female is either 12 months off menstrual period after the age of 50 years, or 12 months off menstrual period after the age of 45 years and FSH \> 40 mIU/mL Note: Amenorrhea should not be due to lactation).
- Participant must be healthy on the basis of their medical history, a physical examination, vital signs, and 12-lead Electrocardiogram (ECG) performed during screening and as determined by the Principal Investigator (PI).

... and 3 more (see full listing online)

Exclusion (21)

- History or presence of cardiovascular, pulmonary, hepatic, renal, hematologic, coagulation, gastrointestinal, endocrine, immunologic, dermatologic, neurologic, or psychiatric disease or any other clinical significant abnormalities during screening investigations which, in the opinion of the PI, may either put the participant at risk because of participation in the study, or influence the results or the participant's ability to participate in the study.
- Evidence of organ dysfunction \[e.g. liver dysfunction; e Upper Limit of Normal (ULN) for ALT, AST or ALP or renal dysfunction (\<90 mL/min of creatinine clearance by Cockroft-Gault formula\] or any clinically significant abnormalities in other clinical laboratory parameters at screening as determined by the investigator.
- QTc (Bazzett) interval e450 ms on ECG at screening.
- Any major surgery requiring general anesthesia within 3 months prior to screening.
- Known or suspected history of alcohol dependency or addictive substance use, as judged by the investigator Note: Participants will be required to abstain from recreational use of soft addictive substances (such as marijuana) within 2 weeks or hard addictive substances (such as cocaine, phencyclidine, crack, opioid derivatives including heroin, and amphetamine derivatives) within 2 months prior to screening

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

Locations (2 total)

Floridian Clinical Research LLC, Miami Lakes, Florida, United States
Synergen Bio Pvt. Ltd., Pune, Maharashtra, India