A Study to Determine Safety, Pharmakokinetics and Efficacy of the Different Doses of VL-SE-01 in Healthy Participants.

NCT06473246

Status	RECRUITING
Phase	Not Applicable
Sponsor	Vedic Lifesciences Pvt. Ltd.
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (8)

- Male \& female individuals must be 18 to 55 years of age inclusive, at the time of signing the informed consent.
- Individuals who are healthy as determined by medical evaluation including medical history, physical examination, laboratory tests, and cardiac monitoring.
- Individual has a body weight of at least 50 kg (males) or 45 kg (females) and body mass index (BMI) within the range 18.5 to 29.9 kg/m2 (inclusive)
- Individuals with a stressed lifestyle as assessed by PSS scores within 27- 40.
- A male must agree to use contraception during the intervention period and for at least 7 days after the last dose of study intervention and refrain from donating sperm during this period.

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

Exclusion (21)

- Individual has a history or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrinology related, haematological, or neurological disorders capable of significantly altering the absorption, metabolism, or elimination of drugs; constituting a risk when taking the study intervention, or interfering with the interpretation of data.
- Males who has a history of oligospermia, vasectomy and other sperm abnormalities.
- Females who have irregularity or problems in menstrual cycles or diagnosed with polycystic ovarian syndrome.
- Individuals with Type 1 and Type 2 Diabetes mellitus and on medication.
- Individuals with SBP e 160 mmHg and DBP e 100 mmHg.

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

Locations (6 total)

Shivam Hospital, Dombivali, Maharashtra, India
Dhanwantri Hospital, Pune, Maharashtra, India
Vedant Multispeciality Hospital, Pune, Maharashtra, India
... and 3 more locations