A Phase I, Open-label, Crossover Study Comparing the Relative Bioavailability of a Fixed-Dose Combination of Laroprovstat/Rosuvastatin vs Their Single Therapy Products in Healthy Adults

NCT07316608

Status	RECRUITING
Phase	Phase 1
Sponsor	AstraZeneca
Enrollment	44 participants

Key Eligibility Criteria

Inclusion (6)

- Provision of signed and dated, written informed consent prior to any study-specific procedures.
- Healthy male and female participants aged 18 to 55 years (inclusive) with suitable veins for cannulation or repeated venipuncture.
- All females must have a negative pregnancy test at the Screening Visit and on admission to the Clinical Unit.
- Females of childbearing potential must not be lactating and if heterosexually active must agree to use an approved method of highly effective contraception, in addition to a barrier method, to avoid pregnancy from the time of first administration of study intervention until 10 days after discharge from the study site.
- Females of non-childbearing potential must be confirmed at the Screening Visit by checking if they are postmenopausal \[amenorrhea for at least 12 months following cessation of all exogenous hormonal treatments and follicle stimulating hormone (FSH) levels in the postmenopausal range\] or by documentation of irreversible surgical sterilization by hysterectomy, bilateral oophorectomy, or bilateral salpingectomy but not tubal ligation or tubal occlusion.

... and 1 more (see full listing online)

Exclusion (37)

- History of any clinically important disease or disorder which, in the opinion of the investigator, 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.
- History or presence of gastrointestinal, hepatic, or renal disease or any other condition known to interfere with absorption, distribution, metabolism, or excretion of drugs.
- Any prior gastrointestinal surgery which may affect absorption, example (eg), gastric bypass or resection.
- Any clinically important illness, medical/surgical procedure, or trauma within 4 weeks of the first administration of study intervention.
- Asian origin.

... and 32 more (see full listing online)

Locations (2 total)

Research Site, Glendale, California, United States
Research Site, Brooklyn, Maryland, United States