

A Drug-drug Interaction Study of Vorasidenib and a Combined Oral Contraceptive in Healthy Female Participants

NCT07235774

Status	RECRUITING
Phase	Phase 1
Sponsor	Institut de Recherches Internationales Servier (I.R.I.S.)
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (8)

- Healthy, nonpregnant, nonlactating pre- or post-menopausal female participants, including women of childbearing potential (WOCBP), assigned female at birth only.
 - years of age (both inclusive) at Screening.
 - Body mass index (BMI) of 18.0 - 30.0 kg/m² (both inclusive) at Screening.
 - Body weight of at least 40 kg at Screening.
 - Participants of childbearing potential who must use two effective methods of birth control (e.g., non-hormonal intrauterine device \[IUD\], male or female condom with spermicide, cap, diaphragm, or sponge with spermicide), or abstinence, from Screening until at least 90 days after the last dose of vorasidenib or who must be surgically sterile (e.g., hysteroscopic sterilization, bilateral tubal salpingectomy, hysterectomy, or bilateral oophorectomy) at least 6 months prior to the first dose of IMP in the study. Participants of childbearing potential must have a negative serum pregnancy test at Screening and prior to the first dose of IMP in the study.
- ... and 3 more (see full listing online)

Exclusion (7)

- Participants of childbearing potential who are pregnant, lactating, or planning to become pregnant within at least 90 days after the last dose of vorasidenib; the participants who are on oral contraceptive pills or contraceptive patch within 31 days prior to the first dose of IMP in the study; participants who use a hormonal IUD or vaginal ring within 3 months prior to the first dose of IMP in the study; or participants who receive any injectable or implantable hormone containing product within 1 year prior to the first dose of IMP in the study.
 - Participant who consume grapefruit or grapefruit juice, or Seville orange or Seville orange-containing products (e.g., marmalade), within 14 days prior to the first dose of IMP in the study.
 - Participant who ingest vegetables from the mustard green family (e.g., kale, broccoli, watercress, collard greens, kohlrabi, Brussels sprouts, and mustard) and charbroiled meats within 14 days prior to the first dose of IMP in the study.
 - Participant who consume caffeine- or xanthine-containing products (e.g., coffee, tea, cola drinks, and chocolate), alcohol, or products containing any of these within 48 hours prior to the first dose of IMP in the study.
 - Participants who are unable or unwilling to abstain from recreational drugs, alcohol, caffeine, xanthine-containing beverages or food (e.g., coffee, tea, chocolate, and caffeinated sodas, colas), grapefruit, grapefruit juice, Seville oranges, or products containing any of these from 48 hours (caffeine, xanthine-containing beverages or food, alcohol) or 14 days (recreational drugs, grapefruit, grapefruit juice, Seville oranges, or Seville orange-containing products) prior to the first dose of IMP in the study until the Discharge/Early Termination visit.
- ... and 2 more (see full listing online)

Locations (1 total)

Celerion, Belfast, Northern Ireland, United Kingdom

<https://clinicaltrials.gov/study/NCT07235774>

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