Evaluation of Tolerance and Pharmacokinetic Profile of High Doses of Favipiravir in Healthy Volunteers

NCT06024421

Status	RECRUITING
Phase	Phase 1
Sponsor	Institut National de la Santé Et de la Recherche Médicale, France
Enrollment	39 participants

Key Eligibility Criteria

Inclusion (16)

- Man between 50 and 75 years old without any desire to have children or woman between 18 and 75 years old ;
- Subject considered healthy after a thorough general examination (questioning, physical examination);
- For men: acceptance of semen collection by masturbation;
- For men: acceptance of condom use from initiation of the investigational drug until 1 month after stopping the investigational drug;
- For women of childbearing potential: effective contraceptive method combining two methods of contraception (one female contraceptive method combined with male condom use) from the inclusion visit until 1 month after discontinuation of the investigational drug;

... and 11 more (see full listing online)

Exclusion (26)

- Concomitant use or within 15 days prior to inclusion of another QT/QTc prolonging drug or drugs that may disrupt electrolyte levels, among others: loop diuretics, thiazide diuretics and related drugs (see list www.crediblemeds.org)
- History of amiodarone use within 6 months prior to inclusion
- History of gout or current treatment for gout or hyperuricemia
- Treatment with pyrazinamide or any other drug known to induce hyperuricemia
- History of hypersensitivity reaction to a nucleoside analog targeting viral RNA polymerase

... and 21 more (see full listing online)

Locations (1 total)

University Hospital Bichat - Claude Bernard, Paris, France

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