A Trial to Investigate the Safety and Pharmacokinetics of GRT6019 in Healthy Male Participants

NCT07347548

Status	RECRUITING
Phase	Phase 1
Sponsor	Grünenthal GmbH
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (3)

- Participant must be male, 18 to 55 years of age (inclusive) at the time of signing the informed consent form and affiliated to the social security system.
- Participant must be capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.
- Participant must sign the informed consent form before any trial-related assessments.

Exclusion (6)

- Any disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, comparator, rescue medication, or any ingredients therein, or may affect the interpretation of the results, or may render the participant at high risk from treatment complications/ participation in the study unsafe
- Major surgical procedure, within 3 months prior to ICF signing, or anticipation of need for a major surgical procedure during the trial
- Clinically significant history or evidence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, neurological, or immunological disorder(s)
- Regularly uses any medication, including herbal remedies or over-the-counter medication within 2 weeks before screening into this trial and anticipated use during the trial
- Concurrent enrollment in another clinical trial, unless it is an observational (non interventional) clinical trial or during the follow-up period of an interventional trial

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

Locations (1 total)

Biotrial Clinical Pharmacology Unit, Rennes, France