Pharmacokinetics, Bioequivalence, and Safety Study of Trimedat® 76,95 mg Orally Disintegrating Tablets and Trimedat® 100 mg Tablets in Healthy Volunteers.

NCT07421011

Status	RECRUITING
Phase	Phase 1
Sponsor	Valenta Pharm JSC
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (38)

- Voluntarily and personally signed informed consent form by a healthy volunteer obtained prior to the conduct of any study-related procedure;
- Males and females aged 18 to 45 years (inclusive) of Caucasian race.;
- Verified healthy status as demonstrated by the absence of clinically significant abnormalities in medical history, physical and instrumental examination, laboratory tests, and other diagnostic procedures specified in the protocol;
- Blood pressure (BP) level: systolic blood pressure (SBP) from 100 to 130 mm Hg (inclusive), diastolic blood pressure (DBP) from 70 to 89 mm Hg (inclusive);
- Heart rate (HR) from 60 to 89 beats per minute (inclusive);

... and 33 more (see full listing online)

Exclusion (11)

- Withdrawal of the volunteer from further participation in the study;
- Non-compliance by the volunteer with the study participation rules (missed study procedures, self-administration of drugs prohibited in the study, violation of dietary and lifestyle restrictions, etc.);
- Emergence of reasons/situations during the study that threaten the safety of the volunteer (e.g., hypersensitivity reactions, etc.);
- Development of a severe and/or serios adverse event (AE/SAE) in the volunteer during the study;
- The volunteer undergoes or requires treatment that may affect the pharmacokinetic parameters (PKP) of the investigational drugs;

... and 6 more (see full listing online)

Locations (1 total)

Federal Budgetary Institution of Science "North-West Public Health Research Center", Saint Petersburg, Russia