

# Safety, Tolerability, and Pharmacokinetic Profile of Grammidin, a Metered Dose Topical Spray in Healthy Volunteers

NCT06859281

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Status	RECRUITING
Phase	Phase 1
Sponsor	Valenta Pharm JSC
Enrollment	24 participants

## Key Eligibility Criteria

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### Inclusion (40)

- 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);
- Verified healthy status as demonstrated by the absence of clinically significant abnormalities in medical history, physical examination, laboratory tests, and other diagnostic procedures specified in the protocol;
- Blood pressure (BP) level: systolic blood pressure (SBP) from 99 to 129 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 35 more (see full listing online)

### Exclusion (12)

- 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 adverse event (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 7 more (see full listing online)

## Locations (1 total)

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Limited Liability Company "Research Center Eco-Safety", Saint Petersburg, Russia

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<https://clinicaltrials.gov/study/NCT06859281>

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