To Investigate Safety, Tolerability, Pharmacokinetics and Pharmaco-dynamics of BAR502 in Healthy Subjects

NCT06705998

Status	RECRUITING
Phase	Phase 1
Sponsor	BAR Pharmaceuticals s.r.l.
Enrollment	52 participants

Key Eligibility Criteria

Inclusion (14)

- Informed consent: signed written informed consent before inclusion in the study
- Sex and Age: men/women, 18-55 years old inclusive
- Body Mass Index: 18.5-30 kg/m2 inclusive
- Vital signs: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, heart rate 50-99 bpm, measured after 5 min at rest in the sitting position
- Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the Investigator and to comply with the requirements of the entire study

... and 9 more (see full listing online)

Exclusion (16)

- ECG 12-leads (supine position): clinically significant abnormalities, in particular QTcF \> 450 ms
- Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study
- Laboratory analyses: clinically significant abnormal laboratory values at screening indicative of physical illness or any acute laboratory abnormality at Screening which, in the opinion of the Investigator, should preclude participation in the study of an investigational compound. INR \> 1.2
- Diseases: significant history of renal, hepatic (in particular, liver or hepatobiliary diseases as indicated by serum alanine aminotransferase, aspartate aminotransferase or total bilirubin levels exceeding the upper limit of normality), gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that may interfere with the aim of the study
- Gallbladder: history of cholecystectomy, presence of gallstones or clinically significant gallbladder abnormalities that may interfere with the aim of the study

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

Locations (1 total)

CROSS Research S.A. Phase I Unit, Arzo, Switzerland