

Efficacy, Safety, and Tolerability of 4-MUST Tablets in Chronic Cholecystitis and Biliary Dyskinesia

NCT06842966

Status	RECRUITING
Phase	Phase 2
Sponsor	Valenta Pharm JSC
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (40)

- Males and females aged 18-70 years.
- Presence of established gastrointestinal diseases: Chronic cholecystitis (K81.1); Dyskinesia of the bile duct or gallbladder (K82.8).
- Presence of pain/discomfort in the upper abdomen combined with at least one of the following symptoms: Heartburn; Belching; Nausea; Abdominal bloating; Borborygmi (stomach rumbling); Flatulence; Constipation; Diarrhea.
- Maximum severity of pain/discomfort in the upper abdomen over the past week is 40 mm or more on the VAS (Visual Analog Scale).
- Severity of gastrointestinal symptoms according to the GSRS (Gastrointestinal Symptom Rating Scale) questionnaire is at least 30 points.

... and 35 more (see full listing online)

Exclusion (10)

- Ineffectiveness of therapy. The therapy will be deemed ineffective if there is no clinical improvement by visit 3 (15±1 days of therapy) - persistence or increase in the severity of pain/discomfort in the upper abdomen on the VAS compared to baseline. If excluded, the patient will be assigned alternative treatment at the discretion of the investigator.
- Patient non-compliance (a compliant patient is defined as one who has taken at least 202 and no more than 303 tablets).
- Requirement for prohibited concomitant therapy.
- If the investigator judges that continued participation in the study would harm the patient.
- Pregnancy or the need for breastfeeding in the patient.

... and 5 more (see full listing online)

Locations (17 total)

State autonomous health care institution "Engels City Clinical Hospital No. 1", Engel's, Russia

Ivanovo Kuvaev Clinical Hospital, Ivanovo, Russia

State Budgetary Institution of Healthcare of Moscow "City Polyclinic No. 2 of the Moscow Department of Healthcare", Moscow, Russia

... and 14 more locations