ISRCTN10602491 https://doi.org/10.1186/ISRCTN10602491

Study of the efficacy and safety of Dipana® in functional gallbladder disorder

Submission date
16/09/2026

Recruitment status
No longer recruiting

Registration date
30/09/2026

Overall study status
Completed

Last Edited
30/09/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Functional gallbladder disorder is a condition in which the gallbladder does not work properly, causing symptoms such as abdominal pain, nausea, bloating and problems with digestion. One type of this condition is hypomotor-type functional gallbladder disorder, where the gallbladder does not contract effectively to release bile. Existing treatments may not always work well for all patients, and some can cause unwanted side effects. Dipana® is a herbal medicine that may help improve gallbladder function and reduce symptoms. This study aimed to assess the effectiveness, safety and tolerability of Dipana® in patients with hypomotor-type functional gallbladder disorder in routine clinical practice.

Who can participate?
Men and women aged 18 to 60 years with a confirmed diagnosis of hypomotor-type functional gallbladder disorder and clinically significant biliary pain were eligible to take part.

What does the study involve?
Participants received Dipana® tablets by mouth, one tablet three times a day, for four weeks. Information was collected at the start of treatment and again after approximately 28 days. Researchers assessed symptoms such as abdominal pain, nausea, bloating, bowel irregularities and fatigue. Pain intensity was measured using a visual analogue scale. Gallbladder function and structure were assessed by abdominal ultrasound before and after a choleretic meal. Blood tests were used to measure liver function and other biochemical markers. Participants also completed questionnaires measuring anxiety levels, and any adverse reactions to treatment were recorded.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
The study was run from the Moscow Regional Research and Clinical Institute (MONIKI), Moscow, Russian Federation.

When is the study starting and how long is it expected to run for?
The study recruited participants between February 2026 and April 2026 and was completed in June 2026. The overall study period ran from February 2026 to June 2026.

Who is funding the study?
Sentiss Rus LLC.

Who is the main contact?
Dr Pavel Rymgaylo, Sentiss Rus LLC, prymgailo@sentisspharma.com.

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Prof Alexey Buyeverov

Contact details
Moscow Regional Research and Clinical Institute ("MONIKI"), st. Shchepkina, 61/2
Moscow
Russian Federation
129110
+7 (499) 674-07-09
bcl72@yandex.ru

Type(s)
Public

Contact name
Dr Pavel Rymgaylo

Contact details
Akademika Pilyugina Street, 22, Algoritm Business Center
Moscow
Russian Federation
117393
+7 (915) 230-97-73
prymgailo@sentisspharma.com

Additional identifiers

Study information

Scientific Title
Observational, non-interventional study of the clinical effect and tolerability of Dipana® in hypomotor-type gallbladder functional disorder in real-world clinical practice

Study objectives

Primary objective:
To study the therapeutic efficacy, safety, and tolerability of Dipana® in patients with hypomotor-type functional gallbladder disorder

Specific objectives:
1. To study the dynamics of pain and dyspeptic symptoms in patients with hypomotor-type functional gallbladder disorder during treatment with Dipana®
2. To assess the sustainability of clinical remission 4 weeks after the completion of the Dipana® treatment course
3. To study the effect of Dipana® on gallbladder motor-evacuation function in patients with hypomotor-type functional gallbladder disorder using abdominal ultrasound
4. To evaluate the tolerability of Dipana® in patients with functional disorders of the biliary system

Secondary objectives:
1. To evaluate the psycho-emotional state of patients with hypomotor-type functional gallbladder disorder during treatment with Dipana®

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/02/2026, Independent Interdisciplinary Committee for the Ethical Review of Clinical Trials (51 Leningradsky Prospekt, Moscow, 125468, Russian Federation; +7 (915) 346 30 30; ethic.com@mail.ru), ref: 03

Primary study design
Observational

Secondary study design
Case series

Study type(s)

Health condition(s) or problem(s) studied
Hypomotor-type gallbladder functional disorder

Interventions
Dipana® was administered orally at a dose of one tablet three times daily for 4 weeks.

In accordance with routine clinical practice, data on patient complaints, medical history, and demographics were collected; clinical manifestations of gallbladder dyskinesia were assessed; abdominal ultrasound was performed; and the patients' psycho-emotional state was evaluated using a standardized written questionnaire.

Follow-up monitoring involved patient examinations and data collection at two visits: Visit 1 (Day 0, baseline)—following the prescription of Dipana® therapy and the signing of voluntary informed consent to participate in the study—and Visit 2 (28 ± 3 days, endpoint).

The impact of Dipana® therapy on the course of clinical symptoms and gallbladder motor-evacuation function was assessed by analyzing changes in the following parameters:

1. Biochemical blood test results (alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase [ALP], gamma-glutamyl transpeptidase [GGT], total bilirubin, total cholesterol, triglycerides, and glucose), measured at Visit 1 prior to the start of therapy and again at Visit 2
2. Clinical symptoms—including complaints of heaviness and pain in the right hypochondrium and epigastric region, bitter taste in the mouth, nausea, bowel irregularities, flatulence, and asthenia—assessed at Visits 1 and 2
3. Patients' subjective assessment of their general well-being at each visit and the physician's assessment of the stability of clinical remission at Visit 2

A visual analog scale (VAS) was used to assess the intensity of pain in the right hypochondrium and epigastrium. Pain intensity was assessed using a 100-mm scale (0 mm = no pain, 100 mm = maximal pain), subsequently categorized into mild (1–30 mm), moderate (31–60 mm), and severe (61–100 mm) pain [15].

The effect of Dipana® therapy on the structural and functional status of the gallbladder (GB) was evaluated via abdominal ultrasound. Changes in GB volume, degree of contraction, wall thickness, and content characteristics were analyzed before and after a choleretic meal (two egg yolks) [16] at Visit 1 (baseline) and again at Visit 2.

Patients' psycho-emotional state was assessed before and after therapy using the Spielberger State-Trait Anxiety Inventory (STAI), adapted by Yu.L. Khanin. The instrument comprises two separate scales, each containing 20 statements, allowing for the independent assessment of state (situational) and trait anxiety levels. Data were collected via standardized questionnaires completed by patients during study visits. A total score ranging from 20 to 80 points was calculated for each scale. Results were interpreted as follows: up to 30 points = low anxiety; 31–44 points = moderate anxiety; 45 points or higher = high anxiety; and over 70 points = very high anxiety.

Tolerability of Dipana® therapy was assessed by analyzing recorded adverse reactions (ARs), including serious ARs.

Intervention Type
Supplement

Primary outcome(s)
1. Clinical symptoms measured using assessment of heaviness and pain in the right hypochondrium and epigastric region, bitter taste in the mouth, nausea, bowel irregularities, flatulence, and asthenia at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

2. Pain intensity measured using a 100-mm visual analogue scale (VAS) at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

3. Gallbladder motor-evacuation function measured using abdominal ultrasound assessment of gallbladder volume and degree of contraction before and after a choleretic breakfast at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

Key secondary outcome(s)
1. Clinical and biochemical outcomes measured using assessment of heaviness and pain in the right hypochondrium and epigastric region, bitter taste in the mouth, nausea, bowel irregularities, flatulence, asthenia, and biochemical blood testing of ALT, AST, ALP, GGT, total

bilirubin, total cholesterol, triglycerides, and glucose at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

2. Gallbladder structural characteristics measured using abdominal ultrasound assessment of gallbladder wall thickness and content characteristics before and after a choleretic breakfast (two egg yolks) at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

3. General well-being measured using patient self-assessment at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

4. Clinical remission stability measured using physician assessment at Visit 2 (28 ± 3 days)

5. State anxiety measured using the State-Trait Anxiety Inventory (STAI) questionnaire at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

6. Trait anxiety measured using the State-Trait Anxiety Inventory (STAI) questionnaire at Visit 1 (Day 0, baseline) and Visit 2 (28 ± 3 days)

7. Tolerability of Dipana® therapy measured using analysis of recorded adverse reactions, including serious adverse reactions, during the study period up to Visit 2 (28 ± 3 days) at the end of the study

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Aged 18 to 60 years, inclusive
2. Presence of biliary-type abdominal pain associated with a diagnosis of functional gallbladder disorder (FGBD), with a clinically significant VAS score of >30 mm (3 points)
3. Patients with a confirmed diagnosis of the condition (K82.8 hypomotor-type functional gallbladder disorder) based on generally accepted diagnostic criteria, who were prescribed Dipana® (one tablet three times daily for a 4-week course) in accordance with the approved product labeling, and who signed the voluntary informed consent form for participation in the program and for the processing of anonymized medical data

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
101

Key exclusion criteria
1. Age under 18 or over 60 years and/or refusal to provide written consent
2. Presence of signs of biliary hypertension or other biliary system pathology requiring surgical treatment
3. Use of antispasmodics or drugs affecting gastrointestinal motility within 28 days prior to study enrollment
4. Pregnancy and breastfeeding (lactation)
5. Established diagnosis of stage II–III alcoholism
6. Severe liver or kidney disease, or psychiatric disorders
7. Severe, decompensated, or unstable somatic diseases (any disease or condition that threatens the patient's life or worsens their prognosis)
8. Any condition precluding the use of Dipana® in accordance with the contraindications, precautions, and special warnings—including those regarding drug interactions—listed in the product's instructions for medical use

Date of first enrolment
16/02/2026

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Russian Federation

Sponsor information

Organisation
Sentiss Rus LLC

Funder(s)

Funder type

Funder Name
Sentiss Rus LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available