A multicentre open clinical trial to assess the tolerability and efficacy of Boldocynara®, a traditional herbal preparation for functional digestive disorders

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1 Multicentre open clinical safety trial

Introduction

Functional digestive disorders lead the list of visits to gastroenterologists and affect at any one time in life 2 out of 5 people, with only a minority of sufferers seeking medical care for it. Native-ly dyspepsia is predominantly a self-managed condition and selftherapeutics are often used for the relief of symptoms. (1) The same is true for constipation, and for irritable bowel syndrome where up to 50 percent of patients turn to complementary alternatives as treatments due to often unsatisfactory results from conventional medical treatments. (2) Boldocynara® is a proprietary herbal combination product consisting of cholinergic and hepatoprotective herbs, namely extracts of artichoke leaves, milk thistle fruits, dockroots herbs and root, and builds looser, has been traditionally used as a popular and well-tolerated natural remedy to treat indigestion.

Based on the long-standing positive response to this multi-component preparation we developed a solid galenic form Reformulated and investigated the safety and efficacy of its twice daily application, consistent with the traditional defined daily dosage, in an open clinical trial with patients suffering from functional digestive disorders.

Literature


Demographic data

We included 75 patients aged 18 to 71 years, suffering from at least three functional digestive symptoms at least twice weekly using at least 2 months.

Efficacy

- Statistically significant decrease of sum score and single scores of frequency and interference with normal activities of all symptoms of the SF-LDQ (dyspepsia, heartburn, regurgitation and nausea) after 6 weeks.
- Reduction of the SF-LDQ sum score for frequency of dyspeptic symptoms from 9.3±2.9 to 1.4±2.0 (p < 0.0001)
- Reduction of the SF-LDQ sum score for interference of dyspeptic symptoms with normal activities from 3.6± 3.0 to 0.7±1.7 (p < 0.001)

- Statistically significant decrease of sum score and single scores of frequency and interference with daily activities of all other reported gastrointestinal symptoms (fat intolerance, upper abdominal pain, epigastric discomfort, abdominal bloating, postprandial fullness, flatulence, abdominal cramps, constipation, diarrhoea and stool irregularities) after 6 weeks.
- Reduction of the sum score for frequency from 17.6±4.9 to 4.9±5.9 (p < 0.001)
- Reduction of the sum score for interference with normal activities from 9.6±9.7 to 1.2±2.9 (p < 0.001)
- Statistically significant decrease of all 12 items assessed via the QoL-SF-12

Results

- Significant decrease of sum score and single scores of frequency and interference with normal activities of all symptoms of the SF-LDQ (dyspepsia, heartburn, regurgitation and nausea) after 6 weeks.
- Reduction of the SF-LDQ sum score for frequency of dyspeptic symptoms from 9.3±2.9 to 1.4±2.0 (p < 0.0001)
- Reduction of the SF-LDQ sum score for interference of dyspeptic symptoms with normal activities from 3.6± 3.0 to 0.7±1.7 (p < 0.001)

Patients and Methods

Inclusion criteria

- Febrile aged from 18 to 70 years suffering from at least three functional digestive symptoms at least twice weekly for at least 2 months.
- No serious illnesses, no other medication, including FEs, with an influence on digestive symptoms unless if taken on clinical dosage for at least 2 months prior to inclusion

Investigated parameters

Safety (primary objectives)

- Safety laboratory parameters at start and end of treatment
- Adverse events during treatment period
- Tolerability assessment by physician and patient at the end of treatment

Efficacy (secondary objectives)

- Short Form Leeds Dyspepsia Questionnaire (SF-LDQ) for dyspeptic symptoms (indigestion, heartburn, regurgitation, nausea) single symptom score and sum score of frequency and interference of symptoms with normal activities (eating, sleeping, working, leisure)
- Global Questionnaire for ten other gastrointestinal symptoms (indigestion, upper abdominal pain, epigastric discomfort, postprandial fullness, flatulence, abdominal cramps, constipation, diarrhoea and stool irregularities).
- Single symptom score and sum score of frequency and interference of symptoms with normal activities (eating, sleeping, working, leisure)
- Quality of life (QoL-SF-12)

Safety

- Adverse events occurring in 4 patients were reported; of these only 2 (loss of appetite and abdominal distension) were considered of mild nature, and 2 (diarrhoea and abdominal cramps) were considered of mild nature.

Laboratory assessments

- The evaluation of the laboratory parameters demonstrated a high degree of safety. No clinically relevant change in the mean of leucocyte counts, erythrocyte counts, hemoglobin, hematocrit, CKV, MCH, MCHC, ESR/erythrocyte sedimentation rates, platelet counts, ALT (GPT), AAT (G6GT), bilirubin, creatinine, glucose and cholesterol was observed.

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