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Research Article

Acid Peptic Disorders

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An Open-labelled, Prospective Clinical Trial to Evaluate the Safety & Efficacy of Alsarex in the Treatment of Acid Peptic Disorders

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Objectives: To evaluate the clinical efficacy and safety of Alsarex Tablets in Acid Peptic Disorders.

Material and Methods: A prospective, open-label clinical study was conducted on 300 patients of both sexes, aged between 18-65 years, confirmed with Acid Peptic Disorders from clinical examination, laboratory tests and who were willing to give informed consent. All patients received Alsarex Tablets at a dose of 1 tablet twice daily half hour before meals for 4 weeks. All patients were evaluated at baseline and 4 weeks using the Gastrointestinal Symptom Rating Scale (GSRS), a validated and standardized tool for assessing symptoms of acid peptic disorders.

Observation: After 4 weeks of treatment, Alsarex Tablets showed significant reduction across all evaluated symptoms in the Gastrointestinal Symptom Rating Scale (GSRS); with p-values less than 0.001, indicating statistically significant reductions in symptom severity after treatment. The greatest improvements were noted in symptoms such as nausea, rumbling in the stomach, and loose stools, where the mean severity scores decreased notably from baseline values. Alsarex showed a broad therapeutic effect across diverse gastrointestinal symptoms, including pain or discomfort in the upper abdomen, heartburn, acid reflux, bloating, burping, and bowel movement irregularities.

Result: Alsarex Tablets were found to be effective and safe in controlling the signs and symptoms of acid peptic disorders and its associated complications. There were no clinically significant adverse events either reported or observed during the entire study period. The overall compliance with the treatment was good and no treatment discontinuations were reported.

Keywords: Alsarex Tablet, Acid Peptic Disorders, Gastrointestinal Symptom Rating Scale (GSRS), dyspepsia, gastric ulcer, duodenal ulcer, Zollinger-Ellison syndrome, functional dyspepsia

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Introduction

Acid peptic disorders encompass a group of gastro-intestinal conditions that arise from an imbalance between aggressive factors, such as gastric acid, pepsin & the protective mechanisms of the gastro-intestinal mucosa. These disorders include common conditions such as dyspepsia, gastroesophageal reflux disease (GERD), gastric ulcers, duodenal ulcers & rarer entities like Zollinger-Ellison syndrome & functional dyspepsia.

They are a major cause of morbidity worldwide, contributing to significant healthcare burden in terms of both treatment costs and loss of productivity due to pain, discomfort, and complications.

Epidemiology: The prevalence of acid peptic disease is found to be very high and significantly associated with increasing age, lower social class, alcohol use, tea use and NSAID use.**[1]** Acid peptic disorders (APDs), including GERD, peptic ulcers, and gastritis, are prevalent worldwide, influenced by age, socioeconomic status, lifestyle factors, NSAID use, and Helicobacter pylori infection. GERD affects 10–20% of adults in Western countries and 5–10% elsewhere, with risk factors like obesity, smoking, and alcohol. Peptic ulcers, declining in developed nations due to H. pylori eradication, still affect 10% of people globally, with duodenal ulcers common in younger individuals and gastric ulcers in older populations. Gastritis, often linked to H. pylori or NSAIDs, may impact up to 50% of the global population, especially in high-prevalence regions.

Risk Factors: Several factors contribute to acid peptic disorders, varying by subtype. Helicobacter pylori infection is a primary cause of peptic ulcers and gastritis, with higher prevalence in developing countries. NSAIDs (e.g., aspirin, ibuprofen) increase ulcer risk, especially with prolonged use. Chronic alcohol consumption and smoking impair mucosal defense and delay healing. Obesity, due to increased intra-abdominal pressure, is strongly linked to GERD and non-H. pylori ulcers. Age-related mucosal changes and increased NSAID use raise the risk in older adults. Genetic predisposition influences GERD and ulcer susceptibility. While diet's role is debated, high-fat, spicy, and acidic foods may worsen symptoms, whereas fibre-rich diets may be protective.**[2]**

Pathogenesis: Acid peptic disorders result from an imbalance between aggressive factors (excess gastric acid, pepsin, H. pylori, NSAIDs) and protective mechanisms (mucus, bicarbonate, prostaglandins). Excess acid and pepsin production, regulated by histamine, acetylcholine, and gastrin, can overwhelm mucosal defences, leading to ulcers. H. pylori infection disrupts the mucosal barrier through urease production, cytotoxins, and inflammation.

NSAIDs inhibit COX-1, reducing protective prostaglandins and increasing mucosal damage. Gastric acid hypersecretion, as seen in Zollinger-Ellison syndrome, worsens acid-related diseases. GERD results from acid reflux due to LES dysfunction. Smoking, alcohol, diet, genetics, and stress further impair mucosal defences, increasing susceptibility to acid-peptic disorders.

The clinical presentation of acid peptic disorders varies widely, ranging from mild dyspepsia and intermittent epigastric pain to more severe and chronic manifestations like persistent heartburn, regurgitation, or weight loss. Diagnosis is typically based on a combination of clinical assessment, endoscopic evaluation, where appropriate, microbiological testing for H. pylori.**[3]**

Conventional Treatment: Acid-peptic disorders, including peptic ulcers, GERD, and gastritis, are managed by reducing gastric acid secretion, protecting the stomach lining, and eradicating *Helicobacter pylori* when necessary. Proton pump inhibitors (PPIs) like omeprazole are first-line treatments, often combined with antibiotics for *H. pylori*-positive ulcers.

If resistance occurs, quadruple therapy with bismuth and additional antibiotics is recommended. H2 blockers and antacids offer alternative relief, while sucralfate aids mucosal healing. NSAID-induced ulcers may require misoprostol. Lifestyle modifications and, in severe cases, surgical interventions are considered. Long-term therapy necessitates monitoring for adverse effects like vitamin B12 deficiency. The goal of therapy is to heal the mucosa, relieve symptoms, and prevent recurrence or complications.**[4]**

Despite significant advances in treatment, however, a substantial proportion of patients continue to experience recurrent symptoms, complications, or inadequate response to current therapies.

Conventional treatments for acid-peptic disorders, including antacids, H2-receptor antagonists, proton pump inhibitors (PPIs), prostaglandin analogues, antibiotics for H. pylori eradication, and lifestyle modifications, each have notable limitations.

Antacids provide short-term relief but do not address underlying causes of disorders & may lead to side effects like constipation or kidney stones with chronic use. H2-blockers[5] can lose effectiveness over time due to tolerance & may not be suitable for severe conditions.[6]

PPIs, while highly effective, carry risks with long-term use, such as osteoporosis, vitamin B12 deficiency, and acid rebound upon discontinuation. Prostaglandin analogues, like misoprostol, are less effective for acid suppression and are often limited by gastrointestinal side effects. Antibiotics for H. pylori may face challenges with resistance, side effects, and patient adherence.

Surgical interventions, though effective in some cases, are invasive and carry inherent risks. Lifestyle changes, while beneficial, often lack sufficient impact on moderate to severe cases and can be difficult for patients to consistently maintain. These limitations highlight the need for individualized treatment plans and the exploration of alternative therapies in certain cases.[7]

This clinical trial aims to evaluate the safety and efficacy of Alsarex, a polyherbal formulation developed by Charak Pharma Pvt. Ltd; in the management of acid peptic disorders.

By assessing the above endpoints, this trial seeks to provide further insights into potential therapeutic options, with the goal of improving patient outcomes and enhancing the overall management of these prevalent and often challenging conditions.

Materials and Methods

Study Design

A non-randomized phase 3, prospective, open label, multi-center clinical trial (N=300)

Study Objectives

Primary: The main objective of the study was to evaluate the clinical efficacy of Alsarex Tablets in acid peptic disorders. Further, the study also observed the clinical safety of Alsarex in acid peptic disorders.

Secondary: To evaluate the reduction in symptoms of acid peptic disorders assessed by Gastrointestinal Symptom Rating Scale (GSRS) by Alsarex Tablets.

Inclusion Criteria:

1. Patients aged 18-65 years who visited the outpatient department with a confirmed diagnosis of acid peptic conditions, such as gastroesophageal reflux disease (GERD), peptic ulcers, or dyspepsia, based on clinical history, endoscopic findings, or laboratory tests
2. Participants exhibiting symptoms consistent with acid-related disorders, such as sour or pungent eructation/belching, retrosternal or throat burning, heartburn, epigastric burning or pain, or regurgitation, nausea, vomiting, unsatisfactory digestion, loss of appetite, heaviness in the body, and tiredness in the absence of physical activity for a specified duration, typically several weeks or more.
3. Patients on prolonged treatment with non-steroidal anti-inflammatory drugs (NSAIDs) for other clinical conditions were also eligible for recruitment, provided they met the other criteria.
4. Eligible individuals willing to provide written informed consent, demonstrate the ability to adhere to study procedures, and having no significant medical conditions or concurrent treatments that might confound study results.

Exclusion Criteria

1. Patients were excluded from the study if they had significant alcohol consumption, were pregnant or breastfeeding, had malignancies, or suffered from other liver, cardiovascular, respiratory, or kidney diseases.
2. Participants with a history of hypersensitivity to the study medication or its components, significant comorbidities such as advanced liver or kidney disease, gastrointestinal malignancies, or other non-peptic ulcer-related gastrointestinal disorders
3. Participants who have undergone major abdominal surgery, particularly involving the stomach or duodenum, were excluded.
4. Additionally, Participants on medications that could interfere with the study drug, such as anticoagulants, NSAIDs, or other acid-suppressive therapies (proton pump inhibitors, H2 receptor antagonists, or other medications affecting gastric acid secretion) were excluded.

5. Participants with a history of substance abuse, or those who were unable or unwilling to provide informed consent or adhere to study procedures and follow-up assessments were also excluded.
6. Finally, participation in another clinical trial within a defined timeframe before enrolment were disqualified to avoid confounding results.

Methodology

A non-randomized phase 3, open label, prospective multi-centric clinical trial in 300 patients diagnosed with acid peptic disorders was planned following required GCP guidelines. After careful selection in terms of the eligibility criteria, screened subjects willing to enrol after explaining the clinical study procedure were requested to sign the Patient Consent Form.

Eligible participants were randomly assigned to receive Alsarex 1 tablet twice in a day half hour before meal for 4 weeks. At baseline visit at 0-day, Patient information sheet was provided to each subject in their language of preference.

Case record form (CRF) was filled by the attending physician with complete medical history and required personal details of the subject at the start of the study.

Clinical assessments

At both the beginning (0-day) and end (28 days) of the study, a physical abdominal examination was conducted, accompanied by the recording of vital signs, including pulse rate and blood pressure. Baseline investigations (shown in table 3) were also performed, which included measuring bleeding time (BT) and clotting time (CT).

To maintain consistency and reduce measurement errors, all assessments were conducted by the same individual. Participants were further evaluated using the Gastrointestinal Symptom Rating Scale (GSRS), a validated and standardized tool for assessing symptoms of acid peptic disorders.

The GSRS includes 15 symptom items such as abdominal pain, heartburn, acid regurgitation, epigastric sucking sensation, nausea, vomiting, borborygmus, abdominal distension, eructation, increased flatulence, changes in flatus passage, stool consistency, urgency of defecation, and feelings of incomplete evacuation.

Each symptom is scored from 0 to 6, where 0 represents no discomfort at all, 1 represents minor discomfort, 2 represents mild discomfort, 3 represents moderate discomfort, 4 represents moderately severe discomfort, 5 represents severe discomfort, 6 represents very severe discomfort.

Intervention

The efficacy and safety of Alsarex, a polyherbal formulation produced by Charak Pharma Pvt. Ltd., were investigated in patients with acid peptic disorders. The treatment involved administering one tablet two times daily half hour before meals with water for a duration of 4 weeks.

Each Alsarex tablet contains a blend of herbs including *Amalaki, Yashtimadhu, Usheer, Oudumbar, Lodhra, Shatavari, Jatamansi, Jeerak* and *Triphala*. Patient evaluations were conducted at baseline (0-day) and end of 4 weeks (28 days) after starting the treatment. Efficacy was assessed by monitoring improvement in laboratory parameters.

Observations

Table 1 shows the Baseline characteristics of patients with acid peptic disorders who participated in our study before intervention. Table 2 shows the effect of Alsarex Tablets after 4 weeks of treatment on the resolution of symptoms of acid peptic disorder, compared to baseline, assessed by Gastrointestinal Symptom Rating Scale (GSRS).

Table 3 shows haematological parameters at baseline and after 4 weeks of treatment with Alsarex Tablets.

Table 1: Demographic data of participants

Number of participants		300
Age (mean ± SD)		42 ± 12 years
Gender	Male (%)	168 (56%)
	Female (%)	132 (44%)
Body Mass Index (BMI)		26.5 ± 3.2 kg/m²
Duration of symptoms	< 1 year (%)	72 (24%)
	1-5 years (%)	150 (50%)
	> 5 years (%)	78 (26%)
Smoking status	Smokers (%)	90 (30%)
	Non-smokers (%)	210 (70%)
Alcohol consumption	Regular (%)	60 (20%)
	Occasional (%)	90 (30%)
	None (%)	150 (50%)

Table 2: Effect of Alsarex on the resolution of symptoms of acid peptic disorder, Gastrointestinal Symptom Rating Scale (GSRS)

SN	Parameter	At Baseline Mean ±SD	After 4 weeks Treatment Mean ± SD	p-value
1.	Pain or discomfort in the upper abdomen	4.03 ± 1.12	3.02 ± 1.02	P<0.001
2.	Heartburn	3.85 ± 0.96	3.14 ± 0.98	P<0.001
3.	Acid reflux	4.12 ± 0.92	3.34 ± 0.95	P<0.001
4.	Hunger pains	4.05 ± 0.96	3.01 ± 0.98	P<0.001
5.	Nausea	4.33 ± 0.95	2.99 ± 0.93	P<0.001
6.	Rumbling in the stomach	4.25 ± 1.03	2.96 ± 1.17	P<0.001
7.	Bloated stomach	4.02 ± 1.01	3.07 ± 1.00	P<0.001
8.	Burping	3.96 ± 0.89	2.97 ± 1.06	P<0.001
9.	Passing gas or flatus	4.24 ± 0.92	3.29 ± 1.09	P<0.001
10.	Constipation	4.01 ± 1.06	2.79 ± 1.01	P<0.001
11.	Diarrhoea	4.23 ± 1.03	3.10 ± 0.87	P<0.001
12.	Loose stools	4.20 ± 0.84	2.92 ± 1.04	P<0.001
13.	Hard stools	3.85 ± 0.92	3.06 ± 0.92	P<0.001
14.	Urgent need to have a bowel movement	4.04 ± 1.09	3.14 ± 1.01	P<0.001
15.	Sensation of incomplete emptying of bowels	3.85 ± 1.03	2.93 ± 0.91	P<0.001

The p-values indicate statistically significant reductions in symptom severity after treatment for all parameters.

Symptoms like Nausea, rumbling in the Stomach, and loose Stools show the most dramatic improvements. The improvement across diverse parameters reflects a broad therapeutic impact of the Alsarex on gastrointestinal symptoms.

Table 3: Effect of Alsarex on haematological parameters

Parameter		At Baseline	After 4 weeks Treatment	p-value
Haemoglobin (g %)		12.95±1.85	13.10±1.92	0.4785
Platelet count (×10³/cu mm)		250 (140-520)	270 (130-540)	0.0035*
Bleeding time (min)		2.50 (1.00-4.50)	2.20 (1.00-4.00)	0.0003#
Clotting time (min)		6.10 (2.50-8.50)	6.40 (2.60-8.70)	0.2900
Liver function tests	Bilirubin (mg/dl)	0.52 (0.15-2.10)	0.53 (0.10-2.40)	0.7950
	SGOT (IU/L)	18.90 (10.50-42.00)	19.30 (3.00-40.00)	0.4050
	SGPT (IU/L)	17.50 (5.50-40.00)	18.20 (6.00-44.00)	0.3200
	Albumin (g/dl)	4.40 (2.80-5.00)	4.35 (2.60-5.20)	0.8700
	Alkaline phosphatase (IU/L)	78.5 (41.50-145.00)	79.0 (39.50-146.00)	0.3100

*P<0.05 as compared to day 0, #P<0.001 as compared to day 0. SGOT=Serum glutamic oxaloacetic transaminase, SGPT=Serum glutamic pyruvic transaminase

Results

A total of 300 patients were enrolled and completed the study within the designated timeframe. At baseline, 56% males (168 participants) and 44% females (132 participants) participated in the trial with mean age of 42 ± 12 years & average BMI of 26.5 ± 3.2 kg/m²², indicating a predominantly overweight population. Participants were categorized based on the duration of their symptoms; 24% had symptoms for less than 1 year, 50% had symptoms for 1-5 years, and 26% had symptoms for more than 5 years. 30% of participants were smokers, while 70% were non-smokers. Regular alcohol consumption was reported by 20% of participants, 30% consumed alcohol occasionally, and 50% abstained from alcohol use (Tablet 1).

After 4 weeks of treatment, Alsarex showed significant reduction across all evaluated symptoms in the Gastrointestinal Symptom Rating Scale (GSRS) including abdominal pain, heartburn, acid regurgitation, epigastric sucking sensation, nausea, vomiting, borborygmus, abdominal distension, eructation, increased flatulence, changes in flatus passage, stool consistency, urgency of defecation, and feelings of incomplete evacuation; with p-values less than 0.001, indicating statistically significant reductions in symptom severity after treatment. The greatest improvements were noted in symptoms such as nausea, rumbling in the stomach, and loose stools, where the mean severity scores decreased notably from baseline values. Alsarex showed a broad therapeutic effect across diverse gastrointestinal symptoms, including pain or discomfort in the upper abdomen, heartburn, acid reflux, bloating, burping, and bowel movement irregularities. Alsarex treatment demonstrated a clear and consistent reduction in symptoms, highlighting Alsarex's potential as an effective therapeutic option for managing acid peptic disorders (Table 2).

Over a 4-week treatment period with Alsarex, there was a slight increase in haemoglobin levels from 12.95 ± 1.85 g% at baseline to 13.10 ± 1.92 g% after 4 weeks.

However, change was not statistically significant (p = 0.4785). A significant increase in platelet count was observed, rising from a baseline median of 250 × 10^3/cu mm (range: 140–520) to 270 × 10^3/cu mm (range: 130–540) after 4 weeks (p = 0.0035*), indicating a positive response to treatment. A decrease in bleeding time was noted from a baseline median of 2.50 minutes (range: 1.00–4.50) to 2.20 minutes (range: 1.00–4.00) after 4 weeks, which was statistically significant (p = 0.0003#). No significant change in clotting time was observed, with values moving from a baseline median of 6.10 minutes (range: 2.50–8.50) to 6.40 minutes (range: 2.60–8.70) (p = 0.2900). In Liver Function Tests, bilirubin level remained virtually unchanged from a baseline of 0.52 mg/dl (range: 0.15–2.10) to 0.53 mg/dl (range: 0.10–2.40) after 4 weeks (p = 0.7950); No significant change was observed in SGOT levels, with baseline values of 18.90 IU/L (range: 10.50–42.00) and 19.30 IU/L (range: 3.00–40.00) after treatment (p = 0.4050) Similarly, SGPT levels remained stable, with baseline values of 17.50 IU/L (range: 5.50–40.00) compared to 18.20 IU/L (range: 6.00–44.00) post-treatment (p = 0.3200). Albumin levels were nearly unchanged, moving from a baseline of 4.40 g/dl (range: 2.80–5.00) to 4.35 g/dl (range: 2.60–5.20) (p = 0.8700). Alkaline phosphatase levels also showed no significant change, with values of 78.5 IU/L (range: 41.50–145.00) at baseline and 79.0 IU/L (range: 39.50–146.00) post-treatment (p = 0.3100) (Table 3). Overall, Alsarex showed significant effects on platelet count and bleeding time, suggesting its potential impact on haemostatic function, while liver function markers remained largely unaffected during 4-week treatment period. Alsarex Tablets were found to be safe and well-tolerated, with no adverse effects reported by any participants.

Discussion

With the modernization of lifestyles, dyspepsia has become a prevalent symptom worldwide. Factors such as polypharmacy due to multiple comorbidities, alcohol consumption, stress, and H. pylori infections have contributed to the rising incidence of acid peptic disorders globally. Acid secretion is regulated by various hormones, receptors, and organs, leading to the use of multiple drug classes—such as H2 blockers, anticholinergics, antacids, prostaglandin analogues, and ulcer protectants—in the management of peptic ulcers.

However, with advent of proton pump inhibitors (PPIs), use of other drugs for peptic ulcers has diminished. Despite their effectiveness, PPIs are not without risks, including potential interactions with clopidogrel, link to gastric carcinoma, & possibility of hypomagnesemia, among other limitations.**[8]**

Conventional medicine has revolutionized the treatment of gastric acid-related disorders. However, their widespread use has brought to light emerging concerns about potential long-term adverse effects that were not previously recognized. These include an increased risk of kidney, liver, and cardiovascular diseases, dementia, gastrointestinal tract enteroendocrine tumours, higher susceptibility to respiratory and gastrointestinal infections, and impaired nutrient absorption. While the existing evidence has not established definitive links, it has raised significant concerns about the safety profile of PPIs, prompting a reconsideration of their clinical indications.**[9]** Despite the limitations of current treatments, there is hope for the development of innovative, effective, and safe management options for the disease. Herbal drugs are alternative remedies for the treatment of various pharmacological conditions and are generally considered to be much safer as compared to synthetic drugs. A number of natural products are reported to exhibit antiulcer property in various animal studies and some of them are currently being used in various herbal formulations. Research into bioactive compounds in foods has emerged as a promising strategy to address the challenges associated with lifestyle modifications. Several natural compounds have shown potential benefits in acid peptic disorders.**[10]**

The fruits of *Phyllanthus* emblica Linn or *Emblica officinalis* Gaertn (Phyllanthaceae), (FPE) commonly known as Indian gooseberry or Amla, gained immense importance in indigenous traditional medicinal systems, including Ayurveda, for its medicinal and nutritional benefits. It is used to cure several diseases such as dyspepsia, colic, flatulence, hyperacidity, peptic ulcer, inflammation, anemia, emaciation, hepatopathy, jaundice, diarrhea, dysentery, hemorrhages, etc.**[11]** Amla (*Phyllanthus emblica* L.), in addition to its nutritional benefits, can serve as a protective agent against gastropathy caused by non-steroidal anti-inflammatory drugs (NSAIDs). It is believed that the therapeutic effects of amla are primarily due to its antioxidative properties.**[12]**

Emblica officinalis has significant amounts of polyphenols, such as gallic acid, ellagic acid & terpenoids, which act as therapeutic agents in different chronic peptic ulcer. Fruit extract of amla is an anti-ulcer agent & pain reducing therapy.**[13]**

Glycyrrhiza glabra (Liquorice) is rich in triterpenoid saponin glycyrrhizin (also known as glycyrrhizic acid or glycyrrhizinic acid), which is usually found in concentrations ranging from 6% to 10%. Its traditional uses include treating peptic ulcers, asthma, pharyngitis, malaria, abdominal pain, insomnia, and infections. The key use of Liquorice is in ulcerative conditions of the gastrointestinal tract (e.g., peptic ulcers, canker sores, inflammatory bowel disease). Rather than inhibiting the release of acid, it stimulates the normal defense mechanisms that prevent ulcer formation and stimulate healing of the damaged mucous membranes. Specifically, it increases the blood supply to the damaged mucosa, number of cells producing the mucus that protects the mucous membranes, amount of mucus the cells produce and life span of the intestinal cell. In addition, several flavonoid components of *G. glabra* have shown significant activity against *H. pylori,* including antibiotic-resistant strains. A study evaluated the effect of licorice in *H. pylori* eradication in 120 patients suffering from dyspepsia either with peptic ulcer disease (PUD) or non-ulcer dyspepsia (NUD), licorice (380 mg twice daily) was given in addition to clarithromycin-based standard triple regimen for 2 weeks. *H. pylori* eradication was assessed 6 weeks after therapy. Response to treatment was 83.3% in the licorice group and 62.5% in the control group.**[14]**

Ficus racemosa is an important medicinal plant, found in India, Australia, and Southeast Asia. It is popular for presence of β-sitosterol. This plant has multiple pharmacological activities that include antioxidant, anti-diarrheal, anti-inflammatory, anti-bacterial and hepato-protective actions. The leaves of this plant are rich in flavonoids, triterpenoids (basically lanosterol), alkaloids, and tannins. A new triterpene namely gluanol acetate and racemosic acid were isolated from the same part. Gluanol acetate is the major component of fruits. The other components are glucanol, tiglic acid, taraxasterol, lupeol acetate, friedelin, and hydrocarbons. The fruit extract (50% ethanol) exhibited antiulcer activity in different well-known animal models of rats with three doses (50, 100, and 200 mg/kg, twice daily, PO) for five days.

The researchers used various animal models like ethanol, pylorus ligation, and cold strain–induced ulcer to perform antiulcer effect. The extract inhibited an ulcer in all above-mentioned models in a dose-dependent manner. A similar extract reduced oxidative damage in mucosal lining of stomach by inhibiting enzyme activity like that of H+/K+ ATPase and superoxide dismutase.**[15]** Therefore, it is observed that the ingredients of Alsarex modulate aggravating factors associated with acid peptic disorders. These findings suggest that Alsarex Tablet is both safe and effective in managing acid peptic disorders and its associated symptoms.

Conclusion

Alsarex Tablets were found to be safe and well-tolerated, with no adverse effects reported by any participants. The present interventional study indicates that Alsarex, a polyherbal formulation is effective and safe in controlling signs and symptoms of acid peptic disorders and its associated complications. There were no clinically significant adverse events either reported or observed during entire study period. The overall compliance with treatment was good and no treatment discontinuations were reported. Alsarex typically target on reducing gastric acid secretion, protecting mucosal lining of stomach and intestines, and enhancing healing of gastrointestinal tract.

Cost of Study

All medications required during the 4 weeks of trial were provided by the sponsor. Bio-chemical test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of SDM hospital, Vidnyanam Clinic & Chaudhari Clinic HCPs who are not associated with the sponsors.

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