

COMPARATIVE CLINICAL STUDY OF POLYHERBAL FORMULATION FOR IBS-C RANDOMISED, THREE-ARM, OPEN-LABEL CLINICAL TRIAL

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ABSTRACT

Irritable bowel syndrome (IBS) is a gastrointestinal disorder marked by abdominal pain, bloating, and altered bowel habits, affecting 4.2%-7.5% of the Indian population. The constipation-predominant subtype (IBS-C) poses significant management challenges, prompting interest in alternative therapies. This study evaluated the safety and efficacy of a polyherbal formulation, the IBS Sure™ tablet, compared to a placebo and mesalamine tablet in 60 IBS-C patients diagnosed using ROME-IV criteria. Participants were randomly divided into three groups of 20 each: IBS Sure™ tablet, placebo, and mesalamine. Over three weeks, the IBS Sure™ tablet group demonstrated significant improvement in complete spontaneous bowel movements (85.0%) compared to placebo (4.0%) and mesalamine (60.0%). Additionally, the IBS Sure™ tablet group showed the greatest reduction in abdominal pain, bloating, stool consistency issues, and straining intensity, along with the highest treatment satisfaction. These findings highlight the IBS Sure™ tablet as an effective, well-tolerated intervention for managing IBS-C symptoms.