Cochrane Central Register of Controlled Trials

irritable bowel syndrome – improvement to the clinical situation by the use of humic acid

ICTRP

http://www.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00005183, 2013 | added to CENTRAL: 31 March 2019 | 2019 Issue 3
DRKS00005183
Links: **WHO ICTRP**

Abstract

INTERVENTION: Intervention 1: Verum (natural humic acid - Activomin®): intake of capsules orally (400mg per capsule) over 28 days (day 1-10: 3x2 capsules daily, day 11-28: 3x1 capsule daily) Intervention 2: placebo (rice flour colored with sepia): intake of capsules orally over 28 days (day 1-10: 3x2 capsules daily, day 11-28: 3x1 capsule daily)

CONDITION: K58 - Irritable bowel syndrome

PRIMARY OUTCOME: Change of IBS-Scores (Irritable Bowel Syndrome-Score, Francis 1997) and therefore the improvement of the subject state while having gastrointestinal dysfunctions on day 28 compared to day 0 (Baseline)

SECONDARY OUTCOME: Safety:; - adverse events ; - rescue medication according to patient diary; - number of patients with premature termination of the trial; efficacy: before and after comparison (day 0 and day 28) for; - Bristol Stool Form Scale ; - IBS-QOL for documentation of quality of life; - Quality of life (SF-36); - further explorative endpoints

INCLUSION CRITERIA: • irritable bowel syndrome - diarrhea-predominant (RDS-D) --> according to ROM III criteria (diarrhea / pain) • male and female patients = 18 years • patients, who are willing and able to realise the study visits (e.g. no planned holidays) • patients, who are willing and able to complete the patient diary • last to weeks (screening phase) at least two times complaints (pain, discomfort) per week • willing to forgo medications of the forbidden medication list • Written informed consent

Information

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