Impact of Additional Treatment With Saccharomyces Boulardii on Quality of Life in Patients With Mild Forms of Ulcerative Colitis and Crohn Disease

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03941418	NOT YET RECRUITING	MAY 8, 2019	MAY 29, 2019

STUDY DESCRIPTION

Brief Summary

The goal of the study is to assess the impact of treatment with dietary supplement containing Saccharomyces boulardii (used as an addition to standard therapy), on quality of life of patients with mild forms of ulcerative colitis and Crohn disease, as well as those in remission fulfilling criteria for irritable bowel syndrome. Patients included will be randomly assigned in two groups and subsequently administered with formulation containing Saccharomyces boulardii or placebo for 4 weeks. Patient's quality of life will be assessed by questionnaire at the enrolment and 4 weeks after initiating the therapy.

Condition or Disease: Ulcerative Colitis
Crohn Disease

Intervention/treatment: Dietary Supplement: Boulardii
Dietary Supplement: Placebo

Phase: N/A

DETAILED DESCRIPTION

Saccharomyces boulardii has been reported to have positive impact on intestinal epithelial barrier as well as immune system. It has been proven to be efficient in treatment and prophylaxis of travellers diarrhoea, HIV associated diarrhoea, antibiotics associated diarrhoea and Clostridium difficile infection. However there is a limited data available on effect of therapy with Saccharomyces boulardii (as add-on to standard therapy) in patients with inflammatory bowel disease. Nevertheless, knowing the effect Saccharomyces boulardii has on intestinal flora, intestinal epithelium and immune system it can be hypothesised that Saccharomyces boulardii used as add-on to standard therapy in IBD patients can lead to improvement in symptoms and therefore in quality of life.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 150 participants

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Impact of Additional Treatment With Saccharomyces Boulardii on Quality of Life in Patients With Mild Forms of Ulcerative Colitis and Crohn Disease

Estimated Study Start Date: June 2019

Estimated Primary Completion Date: March 2020

Estimated Study Completion Date: March 2020

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Boulardii Patients will be administered with formulation containing 500 mg of Saccharomyces boulardii and 10 mg of Vitamin D3 once daily, as an addition to their standard therapy.	Dietary Supplement: Boulardii Patients will be administered with formulation containing 500 mg of Saccharomyces boulardii and 10 mg of Vitamin D3 once daily, as an addition to their standard therapy.
Placebo Comparator: Placebo Patients will be administered with placebo as an addition to their standard therapy.	Dietary Supplement: Placebo Patients will be administered with placebo of same appearance, colour and taste once daily.

OUTCOME MEASURES

Primary Outcome Measures: 1. Patients quality of life [Time Frame: 8 weeks]
Quality of life measured will be measured by questionnaire at day 1, 4 weeks after enrolment and 8 weeks after enrolment. Questionnaire comprises 10 questions considering presence of symptoms of inflammatory bowel disease as well as their effect on well-being. Each question can be answered with one of seven answers contributing 1 to 7 points to final score. Final score ranges between 10 and 70 with higher values corresponding with higher quality of life.

Secondary Outcome Measures:	1. Disease clinical activity [Time Frame: 8 weeks] Disease clinical activity will be measured by Mayo score for ulcerative colitis and Harvey-Bardshaw index for Crohn disease at day 1, 4 weeks after enrolment and 8 weeks after enrollment. The Mayo Score evaluates ulcerative colitis activity based on four clinical parameters. Each parameter of the Mayo score ranges from zero (normal or inactive disease) to 3 (severe activity). The Harvey-Bradshaw index for assessing clinical activity in patients with Crohn disease consists of 5 clinical parameters. Calculation formula for both scores considered the sum of the scores of all the parameters included. Higher values of the score are associated with increased clinical activity of the disease.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- histological diagnosis of ulcerative colitis or Crohn disease
- colonoscopy in last six months confirming mild disease form according to endoscopic criteria (Mayo score, simple endoscopic score)
- colonoscopy in last six months confirming endoscopic remission with fulfilled clinical Rome IV criteria for irritable bowl syndrome
- patients
- patients with mild disease form are eligible only if treated with mesalazine only
- patients in remission eligible for inclusion if treated with mesalazine, biologics, azathioprine or methotrexate
- signed informed consents

Exclusion Criteria:
- no colonoscopy in last six months
- moderate to severe disease according to colonosopy findings (Mayo score, simple endoscopic score)
- indeterminate colitis

CONTACTS AND LOCATIONS

Contacts

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Locations

Sponsors and Collaborators

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Investigator

MORE INFORMATION

Responsible Party :	University Clinic Dr Dragisa Misovic-Dedinje
ClinicalTrials.gov Identifier :	NCT03941418
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Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
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Additional relevant MeSH terms :	*Crohn Disease* *Colitis* *Colitis, Ulcerative* *Ulcer*