

**SACCHAROMYCES BOULARDII IN ACUTE ADULT DIARRHEA.
EFFICACY AND TOLERANCE OF TREATMENT**

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• **Aim of the study:**

Demonstration of clinical efficacy and tolerance of *Saccharomyces boulardii* in patients with acute adult diarrhea.

• **Type of the study**

Placebo-controlled, randomized, multicenter double-blind study.

• **Patients**

92 outpatients (41 women and 51 men), of whom 43 had been treated with active medication and 49 with placebo. The mean age was 38 years.

• **Selection criteria**

The patients should be aged between 18 and 65 years and have acute diarrhea with more than 3 liquid stools during the last 24 hours before visiting the physician.

The exclusion criteria were chronic diarrhea, drug-induced diarrhea, chronic idiopathic enterocolitis (Crohn's disease, ulcerative colitis), bloody stools or concomitant treatment with oral antimycotics.

- **Treatment**

1st and 2nd days of treatment: four capsules three times per day.
From 3rd to the 7th days: two capsules three times per day.
The capsules contained 50 mg of *Saccharomyces boulardii* or a placebo.

- **Assessment criteria**

A comparison of the group treated by *Saccharomyces boulardii* with the control group was performed before the first treatment (day 1) and during treatment on days 3 and 8.
The mean target criteria were the changes in the frequency of stools over the preceding 24 hours and in its consistency.
For the evaluation, both features were combined to give a score.
At the two check-up, a standard faecal culture was done for microbiological diagnosis and the doctors asked about any side effects, tolerability and the success of the treatment.

- **Homogeneity of the group**

There were no significant difference between the placebo and active medication groups as regards age, height, weight and sex.
83% (placebo group) and 88% (treated group) of the patients reported diarrhea lasting for a maximum of 2 days before they went to the doctor.

- **Results**

Under *Saccharomyces boulardii*, significantly more marked reduction in the score for stool frequency and stool quality (main target criterion) than under placebo (-17.2 and -13.6 respectively ; $p = 0.035$) after two days' treatment.
In secondary variables, significant advantage of *Saccharomyces boulardii* over placebo: improvement in nausea (day 3: 78.4% and 51.3% respectively; day 8: 100% and 86.1% respectively) and positive assessment of treatment by patients on day 3 (very good/good 95.1% and 76.1% respectively).

The individual characteristics stool frequency and stool quality were analysed by means of the nonparametric MWU test. The Chi^2 test was applied to the secondary symptoms and to assessment of efficacy and tolerability.

- **Tolerance**

No severe side effects were observed in any patient and the tolerance of the active medication was described by both doctor and patient as «very good» or «good».

- **Conclusion**

«This study demonstrated the overall statistically significant superiority of *Saccharomyces boulardii* over placebo in the treatment of acute adult diarrhea after 48 hours of therapy. This coincides with the positive assessment by patients and doctors. Even on day 8 there is clear superiority ($p < 0.05$) based on the number of liquid stools (score!) and on the secondary symptom nausea.»

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