Raison Testing Service Co., Ltd

Abstract of Clinical Study Report

Study Code	25-RD-04-JJ-001
Study Name	Efficacy of Notrande Shuhuajun Probiotic Supplement on Improving Constipation in Preschool Children
Study Sponsor	Sponsor: Shandong Jiejing Biotechnology Co., Ltd. Address: Building A, 2240 Xinxing Street, Industrial Park, Shanghe County, Jinan City, Shandong Province 251619, China Food Manufacturing License Number: SC10613043000386 Place of Origin: Handan, Hebei Province
Study Duration	From May 30, 2025 to August 24, 2025
Ethics Committee Approval No.	Li Review[2025], No 007
ClinicalTrials.gov Registration No.	NCT07002489 (https://clinicaltrials.gov/study/NCT07002489)
Clinical Study Report Date	December 1, 2025

Objective: Evaluate the effectiveness of Notrande Shuhuajun Probiotic Supplement (Notrande Shuhuajun for short) intake on the improvement of functional constipation in preschool children (3-6 years old).

Study Method: 102 eligible participants will be enrolled in one center and assigned the study product. After one week washout period participants need to take in the product for two weeks, followed by a one-week regression period.
Researchers will collect data, analyze data and conclude whether the study product is effective to improve constipation in participants, by comparing the change of concentration of biochemical indicators SCFA (Short-chain fatty acids), Lactobacillus and Bifidobacterium, and visual analysis of Bristol Stool scale etc.

Result: This study adopted a single-center, single-group open-label design. After a 14-day intervention period with the probiotic product and a 7-day follow-up period, the study primarily evaluated the effectiveness of Shuhujun probiotic supplement in improving the intestinal comfort and reducing constipation symptoms in preschool children. Additionally, the study analyzed the impact of the product on the intestinal microbiota and its metabolites, such as SCFAs, as well as assessed its safety. The results indicated that, compared to the baseline, after 14 days of taking the Shuhuajun probiotic supplement, there were significant improvements in the following indicators for the children:
✓The frequency of bowel movements within a week, the proportion of instances of difficult defecation out of the total number of bowel movements, the duration of each bowel movement, the condition of defecation, as well as the overall intestinal health improved significantly. Symptoms such as abdominal distension, abdominal pain, early satiety, belching, loss of appetite, a feeling of fullness in the stomach after eating, indigestion, nausea/vomiting, poor intestinal motility, and dissatisfaction with digestive function also improved significantly.
✓The frequency of bowel movements increased by 20.6%; the shape of the feces improved significantly, changing from lumpy masses with cracked surfaces to smooth, soft, and sausage-like shapes with clear edges; the color of the feces also changed significantly, shifting from brownish to golden yellow.

✓The abundance of Bifidobacterium in the intestines increased by 73.9%; the abundance of Lactobacillus increased by 36.8%.

✓The levels of acetate, isobutyrate, butyrate, and total SCFAs in the intestines increased significantly, by 14.4%, 12.4%, 13.0%, and 14.7%, respectively.

✓The results of the urine tests showed no significant abnormalities, indicating good safety.

By the end of the decline phase (7 days after the intervention ended, Day 21), the following indicators in the children showed significant improvement compared to the baseline, indicating that the therapeutic effect of Shuhuajun probiotic supplement could be maintained for an additional 7 days after the supplementation was discontinued.

✓The number of bowel movements within a week, the proportion of instances of difficult defecation out of the total number of bowel movements, the duration of each bowel movement, and the quality of the defecation experience. There was also a significant improvement in the overall gut health.

✓Symptoms include abdominal distension, abdominal pain, early satiety, belching, loss of appetite, a feeling of heaviness in the stomach after eating, indigestion, as well as nausea or a desire to vomit.Significant improvements were observed in symptoms such as vomiting, poor intestinal motility, and dissatisfaction with digestive function.

✓The frequency of bowel movements increased significantly by 7.84%. The shape of the feces improved markedly, maintaining a clear edge and a smooth, soft, intestinal-like texture; the color of the feces also remained a golden yellow.

✓The abundance of Bifidobacterium in the intestine increased significantly by 57.0%; the abundance of Lactobacillus increased significantly by 30.7%.

✓The safety profile was satisfactory; a total of 17 adverse events were reported during the study (16.7%). These events included: one case of fever (0.98%), five cases of the common cold (4.90%), one case of conjunctivitis (0.98%), two cases of cough (1.96%), one case of sprain (0.98%), three cases of skin injuries (2.94%), one case of rash (0.98%), one case of burn (0.98%), one case of pharyngitis (0.98%), and one case of otitis media (0.98%). None of these events were related to the study product, and no serious adverse events occurred.