Lactomin Plus Probiotics

Compilation of Abstract

- The Effect of the Microbe Composition *(Lactomin Plus Probiotics)* of This Invention on Treating Diarrhea and Constipation

- Efficacy of Probiotics *(Lactomin Plus)* as an adjunct in Treatment of Bronchial Asthma in Mild Exacebation in Pediatric Patients Aged 6 months – 6 years old at UST Clinical Division

The ***ONLY*** Probiotic Powder form with Double Microencapsulated (NOLTEC Technology) Lactic Acid Bacteria: *Lactobacillus acidophilus and Bifidus longum*

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The First Series of Clinical Study:

The Effect of the Microbe Composition *(Lactomin Plus Probiotics)* of This Invention on Treating Diarrhea and Constipation

Selection Criteria for Patients

Patients suffering various kinds and degrees of diarrhea and constipation were selected to participate in the clinical trials that include:

1. Acute Diarrhea
   (1) Mild acute diarrhea: patients had a temperature below 38°C and diarrhea for no more that 4-5 times per day; feces was in pulpy shape; no purulent discharge could be observed; culture of feces showed negative; there were no other significant clinical symptoms.
   (2) Common acute diarrhea: patients had a temperature around 38-39°C and diarrhea 5-15 times/day; there was purulent or mucus discharge; the number of leucocytes was below 20,000/ml; patients remained fully conscious with normal cardiovascular and respiratory functions; there was no somnolent symptom.
   (3) Acute diarrhea with no clear cause (including bacteria and virus); patients had detrimental eating and drinking habit; the disease occurred abruptly; patients had diarrhea for more than 3 times/day; there was no purulent discharge; the number of leucocytes was below 15 under micro bioscope.
2. Chronic Diarrhea: patients had diarrhea for 2-3 times/day; the shape of feces had been abnormal for 2-3 months; the disease appeared repeatedly and appeared recently again.
3. Constipation: patients suffered from constipation and defecated only once for 2-3 days; the feces were dry and hard; patients often need laxative suppository or lubricant; the constipation had lasted for more than one week.

Design of the Clinical Trials

The clinical trials were designed by the Department of Digestive Internal Medicine and the Department of Clinical Pharmacology of Beijing Friendship Hospital in China according to "the Guideline for Digestive Drug Clinical Research" and "the Technical Requirements on Human Clinical Observation for New Biopreparation" issued by the Ministry of Health of the People's Republic of China. *Double blind and open comparative methods were applied*.

Patients taking part in the clinical trials stopped using other drugs such as antibiotics, hormones, absorbents, astringents or lubricants before the trials began. Standard forms were used to keep the record of the clinical trials data.

540 patients (including adults and children) participated in the clinical trials. Researchers randomized 401 patients into the test group and 139 patients into the control group. Patients in the test group were treated by the microbe composition *(Lactomin Plus Probiotic)* of this convention in the formulation of capsule. Patients in the control group were treated by biofermin also formulated into capsule. There was no difference between the capsules in appearance. The dosage and administrative route were as follows: for adults, 5 capsules each time, 2-3 times a day; for children: 0+-1 years old, 1 capsule each time; 1-6 years old, 2 capsule each time; 6-13 years old, 3 capsule each time; all children took medicine 3 times/day. Composition powder are mix with warm water for baby administration.

Data obtained from the clinical trials were processed according to Ridit and other statistical methods.

From the results of the clinical trials, it can be concluded:

1. The microbe composition *(Lactomin Plus Probiotic)* of this invention is effective in the treating various kinds of diarrhea. The total **effective rate** for the test group was **97.5%** wherein the marked effective rate was 58.6% and the effective rate was 38.9%. The total effective rate for the control group was 50.4% wherein the marked effective rate was 22.3% and the effective rate was 28.1%.

TABLE 11

Effects of the Microbe Composition on Diarrhea **(P <0.05)**			
Group	**Total Effective Rate**	**Marked Effective Rate**	**Effective Rate**
Test	97.5%	58.6%	38.9%
Control	50.4%	22.3%	28.1%

2. The microbe composition is more effective in treating acute diarrhea than chronic diarrhea.

TABLE 12

Comparison of the Effective Rates of the Microbe Composition on Acute Diarrhea and Chronic Diarrhea **(P <0.05)**				
	Total Effective Rate		**Marked Effective Rate**	
	Acute Diarrhea	**Chronic Diarrhea**	**Acute Diarrhea**	**Chronic Diarrhea**
Adults	92.3%	80.0%	76.9%	43.6%
Children	90.7%	76.3%	59.0%	39.0%

3. In addition to treating diarrhea caused by unclear reasons, the microbe composition of this invention is also effective in treating infectious diarrhea caused by dysentery bacteria, salmonellae, pathogenic coliform bacteria, jejunum curved bacteria, pseudomonas acrogened and wheel-like virus. In the test group, 52 patients were determined as being infected by pathogens when they were selected to participate in the trials. 50 of them (96.2%) turned to negative after treatment by the microbe composition *(Lactomin Plus Probiotic)*. The composition was also found markedly effective on all the 8 patients infected by wheel-like virus although they did not take virus detection test after the clinical trials. By contrast, in the control group, only 50% patients infected by pathogens turned to negative after treatment.

4. The microbe composition *(Lactomin Plus Probiotic)* of this invention is effective in treating constipation. Of the six participating patients suffering constipation, the composition was found to be effective on 4 of them.

5. The microbe composition *(Lactomin Plus Probiotic)* of this invention is effective in regulating intestinal flora. In the test group, 19 adults and 16 children were diagnosed to have intestinal flora disorder of different degrees before taking part in the clinical trials, mainly with the symptoms of both the number of entero-bacteria such as aerobic or facultative anaerobic bacteria too high and the number of anaerobic bacteria such as Bifido-bacteria too low. The intestinal flora of these patients recovered to normal condition after treatment by the microbe composition of this invention in the clinical trials.

6. The microbe composition *(Lactomin Plus Probiotic)* of this invention has no side effects.

Expanded program of clinical trial phase III conducted at 80 hospitals in Beijing and Shanghai further tested the efficacy of the microbe composition *(Lactomin Plus Probiotic)* in ***1,321 patients***, including **866 adults** and **455 children**.

The total effective rate to treat acute diarrheal was 95.6% for adults and 91.3% for children. The total effective rate to treat chronic diarrhea was 88.8% for grown-ups and 96.3% for children. The effective rate for treating bacillary dysentery is 94.2% for adults and 92.9% for children while 77.5-94.4% pathogen turn to negative.

The microbe composition (Lactomin Plus Probiotic) was effective not only in treating diarrhea, but also restoring peristalsis in constipation cases. At the clinical trials for treating constipation joined by 94 adults and 61 children, the composition was found to have a marked effective rate of 44.7% and 50.8% for each group while the total effective rate was 77.5% and 88.5% for each group respectively.

EFFICACY OF PROBIOTICS (LACTOMIN PLUS) AS AN ADJUNCT IN TREATMENT OF BRONCHIAL ASTHMA IN MILD EXACERBATION IN PEDIATRIC PATIENTS AGED 6 MONTHS – 6 YEARS OLD AT UST CLINICAL DIVISION

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Objectives. This study determined the effect of Lactomin Plus in the Pediatric Asthma Score, duration of acute asthma episode and identified adverse effects.

Methodology. Experimental Study Design was used. Outpatients at the USTH-CD aged 6 months to 6 years with bronchial asthma in mild exacerbation were included. Thirty four patients had baseline assessment of demographics and initial Pediatric Asthma Score, divided into Group A (control group- 17 subjects) and Group B (experimental group-17 subjects) through simple randomization, Group A received the Conventional treatment (Beta-agonist,Corticosteroids ± Antibacterial), Group B received Lactomin plus,1 sachet mixed in favorite drink given twice a day for 5 days, in addition to the usual treatment of bronchial asthma. They were followed-up for re-assessment of Pediatric Asthma score and duration of asthma exacerbation after 3 days, 7 days and 10 days.

Results. Comparing the percent change in the Pediatric Asthma Score and mean duration of exacerbation before and after treatment showed that experimental group had higher decrease in the Pediatric asthma score than the control group, p value = <0.001.

Conclusion. Treatment with Lactomin Plus showed reduction in Pediatric asthma score and duration of asthma exacerbation.