

## **CLINICAL STUDY**

**1998**

### **BRIEF REPORT: EFFICACY OF THE CLINICAL APPLICATION OF ENTEROSGEL IN THE CLINICAL UNIT OF CHILDHOOD DISEASES OF I.M. SECHENOV MOSCOW MEDICAL ACADEMY**

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#### **INTRODUCTION**

Enterosgel is the organosilicone compound that can selectively adsorb toxic and allergic substances from intestine and blood, prevent their resorption, and favor their excretion from a body. The medication is chemically inert, does not undergo biotransformation, and activates the intestinal peristalsis. The properties of the medication allows its application in treatment of spasmodic asthma, atopic dermatitis with various comorbidity of the GI tract in children.

**RESEARCH OBJECTIVE:** Open-label study of the efficacy and tolerance of the medication Enterosgel in the patients suffered from bronchial asthma and atopic dermatitis.

**SELECTION OF PATIENTS:** Children with the diagnosis of bronchial asthma and atopic dermatitis.

**INCLUSION CRITERIA:** Children of both sexes at the age from 2.5 to 13 years, patients suffered from bronchial asthma of different severity level and atopic dermatitis. The form of bronchial asthma: atopic, mixed.

**EXCLUSION CRITERIA:** N/A.

#### **DOSES AND DOSAGE REGIMEN**

Children at the age from 2.5 to 5 years receive per 1 teaspoon three times a day and children upwards 5 years receive per 1 tablespoon three times a day 2 year before and after meat.

#### **COURSE OF TRIALS:**

**Testing period.** The patients are under observation without administration for 7 days.

**Period of treatment.** The treatment lasted on average 10-14 days.

### **CLINICAL ANALYSIS**

Drug trial was performed in 40 patients. No rejection of the drug therapy was observed. Observations diary was kept for each patient where the followings parameters were recorded: general state, complaints, conditions of skin integuments, data on thorax auscultation, conditions of the organs of gastrointestinal tract (palpatory soreness of abdomen, orexia, stool consistency), and blood analysis.

The entries in the observations diary were made prior to and during treatment using Enterogel (over 5 and 10 days). Besides the recorded data mentioned above, children underwent full laboratory instrumental examination. It included the biochemical and immunological analysis of blood, allergic examination (common and specific immunoglobulin E), investigation of respiratory function, ultrasound investigation of gastrointestinal organs and performing gastroscopy for cause and dysbacteriosis analysis of feces. The routine examinations of urine and faeces were carried out.

Prior to study in all patients with bronchial asthma, chocking fits were noted whose frequency and severity correspond the course of disease. 8 patients were suffered from the severe bronchial asthma and remaining patient were suffered from the bronchial asthma of average severity. At the time of initiation of treatment with Enterogel, the conditions of most patients were satisfactory. All patients had various auscultatory manifestations of disease (dry and moist rales, diminished breath sounds). Eosinophilia was noted in the most (80%) of children. It was on average 12%. No significant changes were found upon immunologic and biochemical analysis. In all patients, an increase in the level of immunoglobulin E was noted and polyvalent sensibilization to food and household allergens was detected. All patients received bronchial spasmolytics (methylxanthines and beta-agonists). 7 patients suffered from the severe bronchial asthma received the inhalant corticosteroids and remaining patient received intal. When investigating the respiratory function, the respiratory obstruction in all patients involved in trials was from 70% to 60% of the normal level.

More than half of patients (22 humans) had comorbid conditions, such as atopic dermatitis. In the most of patients, this disease was at the stage of exacerbation and accompanied by skin oozing lesion to form pyogenic crusts, excoriations, and lichenifications. Many patients had applied antihistamine drugs for arresting of the skin syndrome prior to admission to clinics.

Gastrointestinal diseases were diagnosed in all patients included in the clinical study. 60% of patients had a clinically pronounced exacerbation of gastroduodenitits confirmed by gastroscopy. 65% of patients had a dyskinesia of the gastrointestinal tract and bile passages. Dysbacteriosis was

detected in 20% of patients. The correction of comorbidity was performed by additional administration of antacidic and enzymatic drugs.

Improvement was noted in Day 3 after introduction of Enterosgel into the therapy: in patients, choking fits were terminated, manifestations of skin syndrome remitted, and gastrointestinal functional improved. The clinical reduction of obstructive syndrome was noted in 50% of patients in Day 5 of treatment. Normalization of the respiratory functions occurred in Day 14 of treatment and, in the patients with the severe bronchial asthma, in the third week of treatment with Enterosgel. Abdominal pains disappeared and stool was normalized. In children with the atopic skin manifestations, a significant regression of skin syndrome was noted on average at Day 5. The complete remission was achieved in 85% of patients in Day 10 of medication taking. The number of eosinophiles decreased according to the blood analysis.

A comparison with the control group of children suffered from analogous pathology and received no drug was made. Their treatment included the use of the drugs mentioned above. The analysis of results showed significant improvement of the clinical pattern of bronchial asthma and its comorbidity in the group of patients received Enterosgel by 7-10 days earlier compared to the control group. Besides the positive clinical changes mentioned above, reduction of any inflammatory changes on skin was noted, in particular, the disappearance of serum rash caused by the error in dietary for 6 hours after Enterosgel administration. Considerable decrease in acne vulgaris was noted in adolescents. Enterosgel approved itself as a highly-active drug upon food poisoning. The dyspepsia symptoms were arrested 2-4 hours after administration (3 patients). A decrease in the body weight due to normalization of feeding rhythm was also noted upon outpatient observation (a decrease in the body weight was diagnosed in 3 immature girls suffered from overweight) No adverse effects were observed. There were complaints of astringency. In general, the drug tolerance was high.

## **CONCLUSIONS AND PRACTICAL GUIDELINES**

The medication Enterosgel offered by the enterprise "SILMA" approved itself as the efficient agent for treatment of various allergic pathology. Taking of Enterosgel by patients having the atopic genesis of bronchial asthma and dermatitis helps to arrest the broncho-obstructive syndrome and skin syndrome due to adsorption of allergens. Enterosgel allowed patients to withdraw from antihistamine drugs, reduce the administration time of bronchial spasmolytics. It showed a high clinical activity in the therapy of both acute and chronic digestive diseases.

Thus, Enterosgel is the efficient supplement to conventional treatment of allergic and gastrointestinal diseases in children.

*According to the "Report of the clinical unit of childhood disease of I.M. Sechenov Moscow Medical Academy on the clinical trial of Enterosgel". Clinical unit of I.M. Sechenov Moscow Medical Academy, Moscow, 1998.*