

# **Efficacy and safety of medical device Nasaval in prevention and treatment of persistent allergic rhinitis in adults and children**

Zakharzhevskaya TV, Sidorenko IV, Treskunov VK, Karaulov AV  
Sechenov Medical Academy, Moscow

This was presented at Moscow XVI Congress for Men and drug April 06-10, 2009.

*Keywords:* persistent allergic rhinitis, Nasaval, ultra-disperse cellulose powder, clinical trial

## **Summary**

This paper describes the findings of an open non-comparative clinical study of efficacy and safety of an ultra-disperse cellulose preparation in prevention and treatment of persistent allergic rhinitis (AR).

## **Introduction**

Allergic rhinitis is a condition characterized by allergic inflammation, resulting from contact of allergens with nasal mucosa and associated with one or more of the following symptoms:

1. Nasal congestion
2. Nasal discharge
3. Sneezing
4. Nasal itching (1).

AR is one the most widespread allergic diseases. Not infrequently, it precedes other allergic disease, such as atopic dermatitis and bronchial asthma. Active manifestations of AR have a significant impact on the patient's quality of life, interfere with sleep and rest, and decrease capacity for work.

Methods of preventing and treating AR, which are currently available in an allergist's armamentarium, are not completely effective, are time-consuming, costly and associated with a number of side effects. The challenge of finding adequate means to prevent and treat AR is further aggravated in children and pregnant women, due to the lack of evidence confirming the safety of such medications in these categories of patients.

The usage of ultra-disperse cellulose may become a method of choice to prevent and treat AR.

After the registration and approval of microcellulose powder for medical application in Russian Federation, this open non-comparative study was conducted in 2009 to investigate the effectiveness and safety of medical device Nasaval in prevention and treatment of allergic rhinitis.

## **Study design**

Forty eight patients with persistent allergic rhinitis were included into the study. The group consisted of 25 adults and 23 children of both genders, aged 2 to 62 years. The patients were examined weekly over the observation period of 4 weeks. Children were accompanied by their parents during their visits to the trial centre. At study enrollment, the patients were asked for their verbal and written informed consent, according to a form developed for this study in

accordance with the Helsinki Declaration. One of the parents was requested to sign the consent form for an under-aged child.

In accordance with the study protocol, an individual record form was filled out for each patient and included passport data, initial case history and examination findings as well as the findings of follow up visits during the course of the study.

- The patients received one puff Nasaval into each nostril 3 times a day over the course of 4 weeks. In case of insufficient effect they were allowed to use the preparation more frequently.
- The patients visited the investigator weekly, i.e. 4 times during the study period. The severity of AR symptoms and the tolerability of the product were assessed during each visit.
- The patients filled out a quality of life questionnaire and a visual analogue scale during initial and final visits.
- The effectiveness of treatment was assessed by investigator together with the patient (in case of children together with the parents) during the final visit.
- The patients were maintaining a diary with daily records of severity of AR symptoms, any side effects and need for other medications.

## Subjects

Patients, who were enrolled into the study, came to the initial visits with a confirmed diagnosis of AR, supported by the findings of allergen tests and rhinoscopy.

*Figure 1. Characteristics of the study group.*

Parameter	Adults n=25	Children n=23
Age	18 to 62 years Mean - 40.2 years.	2 to 18 years Mean - 10.8 years
Duration of AR	13.8 years (2-40)	5.75 years (1-15)
Bronchial asthma	68%	24%
Atopic dermatitis	-	8%
Pollenosis	64%	79%
Epidermal allergy	82%	79%
Nutritional allergy	36%	33%
Family history of allergy	68%	92%
Drug allergy	23%	12%

Figure 1 demonstrates that most of the subjects had several concomitant types of allergy. Household and epidermal types of sensitization were most common. The presence of various allergy types was revealed by history taking and allergen tests. Concomitant bronchial asthma, nutritional or drug allergy was observed in many of the subjects. Nutritional and medicamentous types of sensitization were commonly manifesting as nettle rash, and sometimes as asthmatic attacks. Most of the subjects had a family history of allergy. Therefore, AR was associated with

other atopic conditions in most subjects of the study group. The sensibilization spectrum of the study group is presented in Figure 2.

Figure 2. Forms of sensibilization found in study subjects during allergen tests.

Types of allergens	Adults (n=25), %	Children, (n=23), %
<i>Dermatophag. Pteron.</i> <i>Dermatophag. Farine</i>	100	100
<b>Pollen</b>	64	79
<b>Thereof:</b>		
<b>Trees</b>	79	89
<b>Cereals</b>	43	74
<b>Weeds</b>	21	52
<b>Allergy to 2 or 3 types of pollen:</b>	57	68
<b>Epidermal allergy</b>	82	79
<b>Thereof:</b>		
<b>Cat</b>	94	89
<b>Dog</b>	50	79
<b>Horse</b>	11	21
<b>Hamster</b>		5
<b>Allergy to 2 or more epidermal allergens:</b>	50	68

With regard to the data in Figure 2, the following conclusions may be drawn. Firstly, all subjects enrolled in the study were sensitized to house dust mite allergens. Secondly, house dust mite allergy was frequently concomitant with epidermal and pollen allergies. The structure of sensibilization types was virtually similar in children and adults. A combination of household allergy with sensibilization to cat epidermis and tree pollen was very frequent in all age groups.

When interviewed, all patients participating in the study complained of the symptoms of actively manifesting AR of various severity grades: sneezing, nasal and nasopharyngeal itching, eyelid itching, nasal discharge, impaired nasal breathing. All symptoms were assessed for severity grading:

0. Absent (no symptoms)
1. Mild (symptoms do not influence the lifestyle)
2. Moderate (symptoms have a moderate impact on everyday lifestyle)
3. Severe (symptoms have a significant impact on the patient's lifestyle and interfere with normal everyday activities).

## Findings

Figures 3 and 4 demonstrate the improvement of AR symptoms in both adults and children in the course of regular administration of disperse cellulose powder.

Figure 3. Evolution of AR symptoms in the course of 4 week treatment with Nasaval in adults.

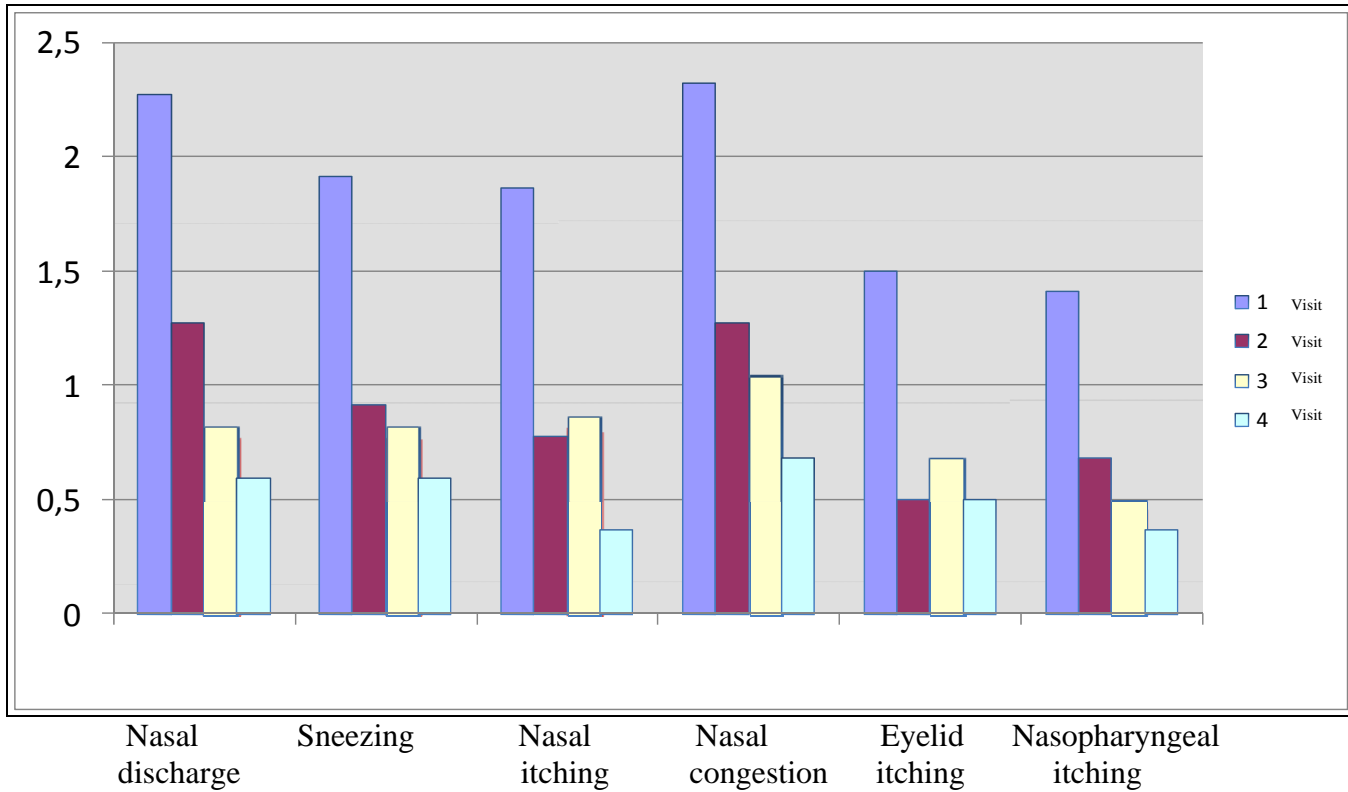
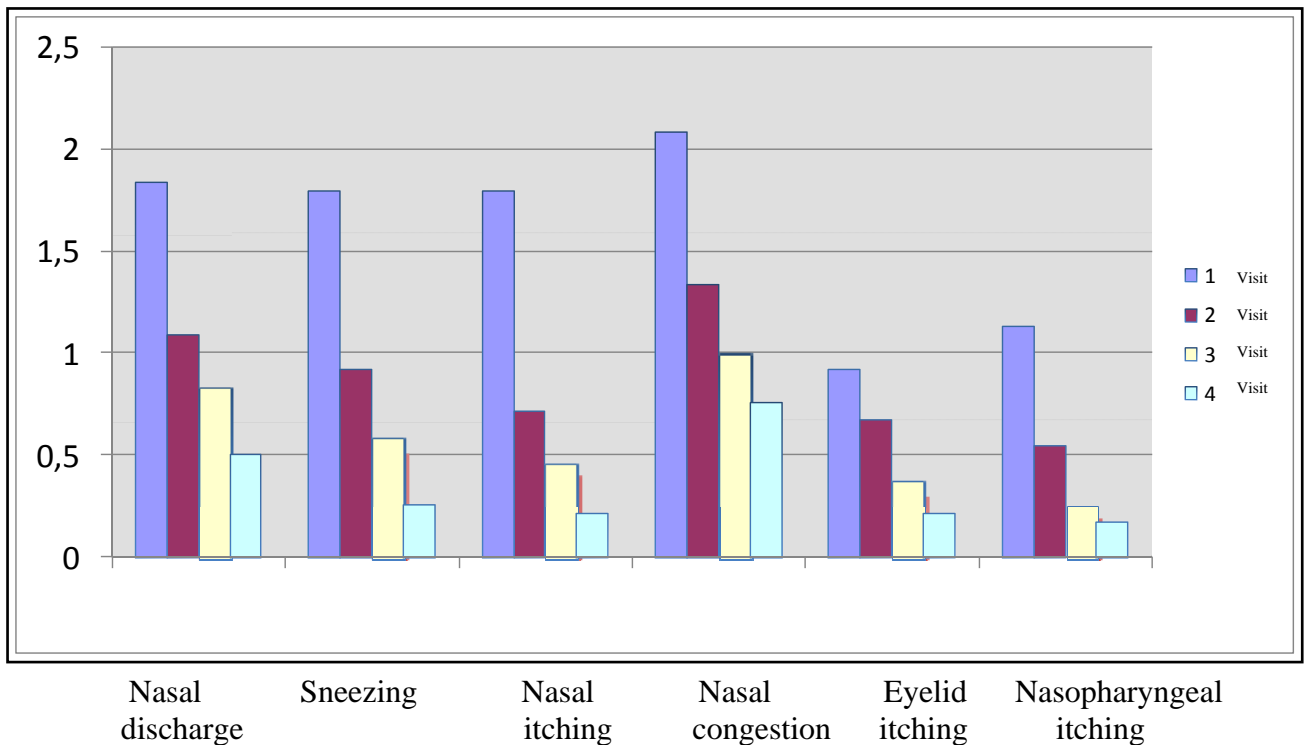


Figure 4. Evolution of AR symptoms in the course of 4 week treatment with Nasaval in children.



Analysis of the data presented in Figures 3 and 4 demonstrates that the effects of microcellulose had an early onset. Improvement of all AR symptoms was observed already in the first week of therapy, and was especially significant by the end of the study period, both in children and in adults.

The following case record illustrates this trend: A 25-year old woman was diagnosed with perennial moderate allergic rhinitis 20 years ago. Allergy tests confirmed allergy to house dust mite and pollen of cereals and weeds. Family history includes allergic rhinitis in father and brother. Improvement of AR symptoms in the course of 4-week therapy with microcellulose powder is presented in Figure 5.

*Figure 5. Effects of Nasaval therapy on symptom scores in a 25 year old patient.*

	<b>Nasal discharge</b>	<b>Sneezing</b>	<b>Nasal itching</b>	<b>Nasal congestion</b>	<b>Ocular itching</b>	<b>Nasopharyngeal Itching</b>
<b>Initial symptoms</b>	<b>3</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>1</b>	<b>0</b>
<b>Study week 1</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>Study week 2</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>
<b>Study week 4</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>0</b>
0. Absent (no symptoms) 1. Mild (symptoms do not influence the lifestyle) 2. Moderate (symptoms have a moderate impact on everyday lifestyle) 3. Severe (symptoms have a significant impact on the patient's lifestyle and interfere with normal everyday activities).						

Overall assessment of the outcomes of 4-week therapy with Nasaval was conducted during the final visit. The investigator assessed the overall efficacy of cellulose micropowder together with the patient. The patients' judgement was based on their sensation of the symptoms, while the investigators analyzed the evolution of AR symptoms, visual scale scores, and the findings of the quality of life questionnaires. The results are summarized in Figure 6.

*Figure 6. Assessment of the efficacy of Nasaval.*

Effectiveness	Adults (% of all adult subjects)	Children (% of all pediatric subjects)	Total (% of all subjects)
Very good	45	38	41
Good	50	62	57
Moderate	5	-	2
No effect	-	-	-

As it can be noted from the data in Figure 6, therapy with microcellulose powder was effective in varying degrees in all patients participating in the study. The majority of both adults and children (in the latter case the feedback was as a rule collected from the parents) assessed the efficacy of the product as good or very good.

Effectiveness of treatment is further confirmed by the improvement in quality of life of the patients treated with Nasaval. The questionnaire, which was used to assess quality of life of AR patients before and after 4 weeks of treatment with cellulose powder is presented in Figure 7.

Figure 7. AR patient quality of life questionnaire.

<u>Types of activity</u>	1. Usual activities at home and at work; 2. Communication; 3. Outdoor activities
<u>Sleep</u>	4. Difficult to fall asleep 5. Awakening during the night 6. Difficult to wake up
<u>General symptoms</u>	7. Fatigue 8. Thirst/dryness in the mouth 9. Decreased capacity for work 10. Sluggishness 11. Concentration problems 12. Headache 13. Depression
<u>Practical problems</u>	14. Must always carry tissues 15. Must rub nose and eyes 16. Must blow the nose all the time
<u>Nasal symptoms</u>	17. Nasal congestion 18. Nasal discharge 19. Sneezing 20. Postnasal drip
<u>Ocular symptoms</u>	21. Itching in the eyes 22. Epiphora 23. Pain 24. Swelling around the eyes
<u>Emotional condition</u>	25. Frustration, anger 26. Impatience, anxiety. 27. Irritation 28. Uneasiness.

Assessment scale:

0 – not disturbing

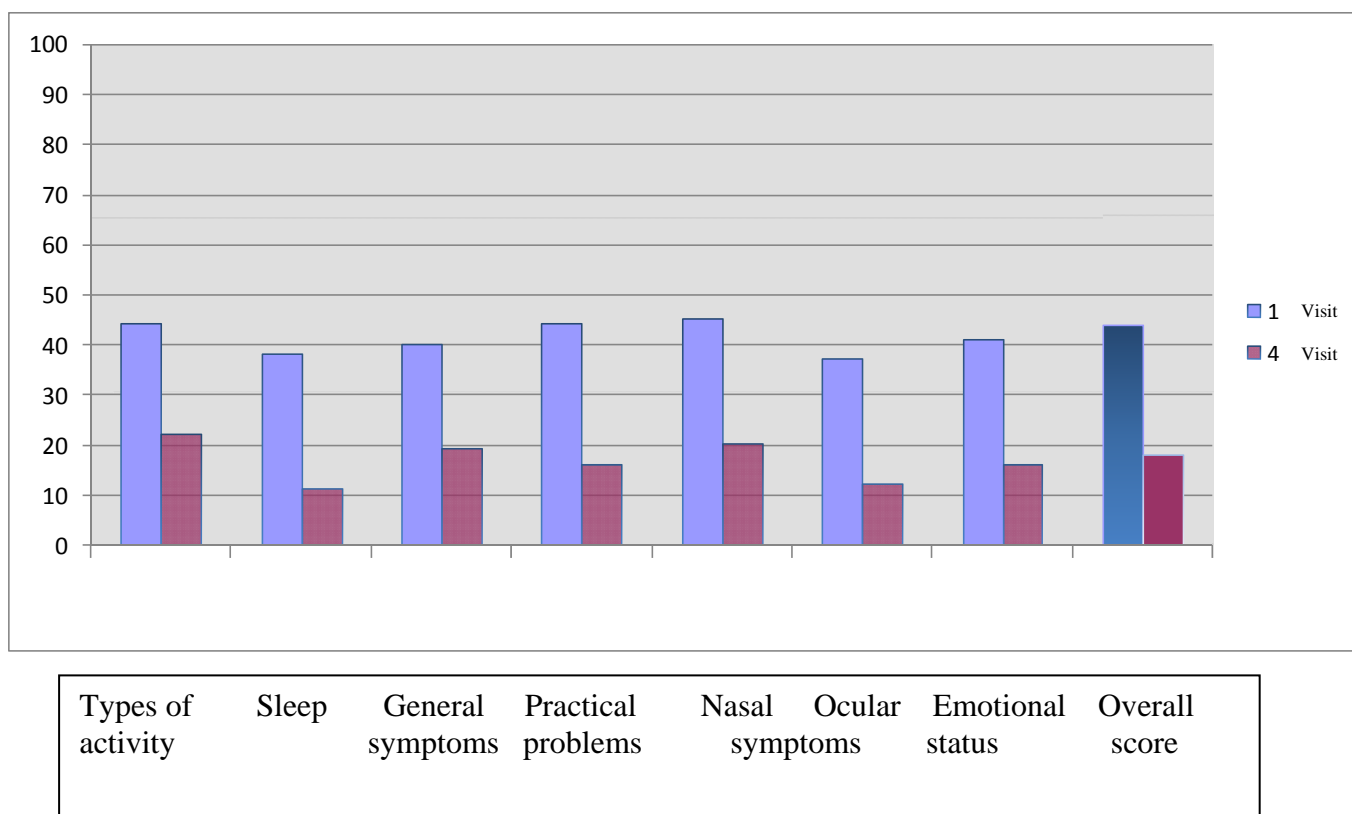
1 – almost undisturbing    3 – moderately disturbing    5 – very significantly disturbing

2 – slightly disturbing    4 – significantly disturbing    6 – extremely disturbing

The questionnaire covers various aspects of the patient's life, his/her physical and emotional condition and other factors, which may be negatively affected by AR.

The findings of the questionnaires are analyzed in Figure 8.

Figure 8. Assessment of quality of life by the patients before and after therapy with Nasaval. (Scale of assessment: 100 % - Maximal impact of the disease on quality of life.)



It can be observed from the data in Figure 8, that quality of life of AR patients improved more than twofold in the course of treatment with microcellulose powder.

Both patients and investigators assessed the tolerability of Nasaval. This assessment is summarized in Figure 9.

Figure 9. Tolerability of Nasaval

Tolerability	Adults (% of total adult subjects)	Children (% of total pediatric subjects)
Very good	95	87
Good	5	9
Moderate	-	4
Poor	-	-
Description of unwanted effects	<ul style="list-style-type: none"> <li>• Formation of crusts in the nose during 4 first days of therapy – 2 patients;</li> <li>• Burning in the nose – 1 patient</li> </ul>	<ul style="list-style-type: none"> <li>• Burning in the nose – 1 patient</li> <li>• Itching in the nose, sneezing for 1 hour after administration – 1 patient</li> </ul>

As a rule, both children and adults reported good or very good tolerability of microcellulose powder. Occasional unwanted effects included: formation of crusts in the nose, burning in the nose, sneezing. These symptoms occurred in isolated cases and did not lead to discontinuation of therapy.

### **Conclusions**

1. Nasaval reduces the severity of AR symptoms already in the first week of treatment.
2. Nasaval therapy is associated with a more than twofold improvement in the quality of life of AR patients
3. Therefore, Nasaval is an effective and safe method of prevention and treatment of allergic rhinitis both in adults and children.
4. Microcellulose powder is capable of creating a natural safe barrier protecting the airways from contact with allergens and oxidating pollutants.

### **Literature**

1. Ilyina NI, Sidorenko IV. Allergic Rhinitis. Physician education program. RAAKI. Akrihin. Moscow. 2003.