Use of Nasaleze Cold as Prevention Method for Acute Respiratory Illnesses in Pediatrics

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Use of Nasaleze Cold as a prevention method for acute respiratory illnesses in paediatric practice

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Acute viral respiratory infections are the most common childhood pathology. Every year, there are one to eight respiratory infections per child per year. The relevance of using prevention measures for viral respiratory infections is confirmed by the dynamics of incidence of the illness. Based on Rospotrebnadzor (Russian Federal Consumer Rights Protection and Human Health Control Service) data, the incidence of acute infections of the upper respiratory tract in May to December 2009 has grown by 3.5% compared with the same period in 2008 [1]. Children of all age groups are equally involved in the epidemic process. The average illness incidence in children from 0 to 2 years was 38.2% (for the 2008 epidemic season - 36.86%), three to six years - 43.5%, (41.9%), among schoolchildren - 27.3% (26.3%), and in persons over 18 years - 18% (15%) [2]. The highest incidence of the illness is noted among children of pre-school and primary school age. It is possible that adverse external factors also lead to an increase in the incidence of the illness (passive smoking, environmental pollution, living in industrial areas). The aetiology and clinical manifestations of URTI are varied, impeding the diagnosis and treatment of viral infections. Immunity after past URTI is type-specific, which results in repeat cases of illness. [3] The existing prevention methods are sufficiently well-developed but not always effective. Measures include: restricting the child's contact with people suffering from respiratory illnesses, ensuring good sanitation and hygiene, reduction in the use of public transport, extending the time the child spends in the fresh air and immunisation. However, children regularly attend formal establishments and it is possible to get infected at home, by parents, relatives and other children [4].

The high level of incidence, the severity of the diagnosis (especially in children of preschool and primary school age), the possible development of complications and the considerable socio-economic element of URTI result in a need to develop and put into practice effective preventive methods [5].

There are new opportunities for preventing respiratory infections through the use of the locally acting drug Nasaleze Cold. The drug consists of natural components - microdispersed cellulose powder and plant-derived wild garlic extract - which are sprayed from the vial onto the nasal cavity mucosa. A peppermint extract is also included as an auxiliary substance, giving a pleasant taste and odour to the powder. The preparation is a nasal powder spray acting as an "invisible mask", protecting the nasal mucosa from viruses and bacteria [6].

Upon contact with the nasal cavity mucus, the micronised cellulose (polysaccharide-cellulose obtained from plant cellular membrane) forms a gel-like coating that protects the body from microparticles that are inhaled in the air (viruses, bacteria, allergens, pollutants). [7] The wild garlic extract included in the drug composition has been used in medicine for over 5000 years, contains essential oils, a high amount of vitamin C and phytoncides. Phytoncides (from Greek *phytón* - plant and Latin *caedo* - to kill) are biologically active substances formed by plants, which detoxify or suppress the growth and development of microorganisms. The active substances in garlic are allicin and ajoenes, which have a proven anti-bacterial, fungicidal and anti-viral effect (the anti-viral effect is more pronounced in ajoenes). [8] As opposed to anti-biotics and anti-viral drugs, microorganism resistance does not develop for phytoncides.

The product is issued in the form of a dry spray in a special 500 mg bottle that dispenses the exact dose. A gel-like layer is formed on the nasal mucosa, acting as a natural barrier or filter against viruses and bacteria inhaled in the air, and breathing is not affected. Nasaleze Cold can be used prophylactically for daily defence against URTI during an epidemic season, for emergency protection before coming into contact with someone suffering from an infection, in places of mass public gathering or prior to journeys on public transport. Prescription is twice a day.

If required (after sneezing or blowing nose) it is recommended to repeat the spraying to restore the protective coating.

Aims and objectives.

An open comparative randomised study of the efficacy and safety of using microdispersed cellulose powder (Nasaleze Cold) for the prevention of respiratory viral infections in children was carried out over six weeks in the season from December 2009 to January 2010.

The study was based at the outpatient department of the Children's Diseases Clinic of the I.M. Sechenov Medical Academy, Moscow, as well as at the Tula Municipal Centre for Paediatric Respiratory Pathology. Parents of children included in the study were informed about the method of preventing respiratory infections. Monitoring included 63 patients aged three to 14 years who suffered from acute respiratory infections almost every month (from six to 12 times a year). 43 children were prescribed Nasaleze Cold. 20 children in the comparison group received symptomatic treatment. There were 28 girls (44%) and 35 boys (56%) and the average age was 6.8 ± 2.5 years.

Inclusion criteria for the programme were as follows: outpatients three to five years old and outpatients six to 12 years old; informed consent of the patient's parents for taking part in the study; no URTI symptoms; no heightened sensitivity to any of the product's ingredients.

Exclusion criteria for the study were as follows: hypersensitivity and/or contraindications for any ingredients of the investigative product; inability to follow medical recommendations; presence of somatic disorders that may worsen in the course of the patient's participation in the programme; no written consent for taking part in being monitored; patients suffering from severe forms of chronic illnesses; discontinuation of taking part in the programme. The reasons for patients' early withdrawal were: erroneous inclusion in the study; patient's desire to leave the study, deviation from the programme (non-observance of doctor's recommendations with regard to the investigative product); occurrence of severe adverse events calling for withdrawal of the investigative product.

Developing URTI symptoms during the period of observation was not an indication for discontinuing Nasaleze Cold. The patients were monitored for six weeks.

Throughout the observation period, the state of nasal breathing at night and during the day, discharge from the nasal cavity and its characteristics, sneezing and coughing were all evaluated daily on a 5-point scale (where 0 points - no symptoms; 1 point - symptoms appear but do not bother the patient significantly; 2 points - manifestations of the illness cause moderate discomfort, 3 points - symptoms are pronounced, they reduce the patient's activity and affect sleep, 4 points - manifestations of the illness are expressly pronounced, they significantly reduce the patient's activity and negatively affect sleep). Body temperature, intoxication symptoms (headache, lack of energy, drowsiness, restless sleep), tolerance of the drug based on presence/absence of allergic reactions and other side effects were also evaluated.

Parameters were monitored at weeks two and six after starting use of the drug. The Nasaleze Cold medical device was used in accordance with the recommended dosage: one spray into each nostril twice a day. Patients were recommended to re-spray Nasaleze Cold after each time they blew their nose or when likely to come into contact with someone suffering from URTI in order to restore the protective layer.

All patients taking part in the study belonged to the group of children who are frequently ill (URTI 6-10 times/year). The comparison group consisted of 20 children, (control group) comparable in age and gender, not receiving treatment with Nasaleze Cold spray.

Permissible therapy: vitamins and drugs that have to be taken for concurrent conditions, provided they are not included in the list of drugs not permitted for use during the study.

Prohibited therapy during the treatment was taking other nasal medical preparations as well as drugs for prevention of URTI (Grippferron, Viferon, Arbidol etc.)

Study group characteristics.

Data regarding objective and subjective URTI symptoms during and after use of Nasaleze Cold was evaluated. These indicators were compared with the same ones in the group of patients who did not receive preventive treatment with the product and with the same period in the previous year for patients receiving Nasaleze Cold. The results were recorded in the "Patient observation diary".

The average age of patients in the main group (1) and comparison group (2) was 6.9 ± 2.5 and 7.1 ± 3.2 years accordingly. By the start of the study the frequency of URTI for the past three months in both groups was 2.92 ± 1.3 and 2.84 ± 1.78. The frequency of URTI in the previous year in these groups was 2.72±1.11 and 2.79±1.7.

A similar number of children with concurrent allergic conditions and illnesses of the ENT organs was noted in both groups. (Table No. 1)

Table 1. Patient medical history characteristics

GROUPS	MAIN		CONTROL	
	%	Number of children	%	Number of children
Obstructive bronchitis	7.7%	3	10%	2
Bronchial asthma	23%	9	25%	5
Allergic rhinitis	31%	12	30%	6
Atopic dermatitis	10%	4	12.5%	2
Chronic tonsillitis	3.12%	8	5%	1
Adenoids	28.25%	11	25%	5
Chronic rhinopharyngitis	10.2%	4	10%	2

At the start of the study the patients had not received any other drugs for the prevention of URTI.

The patients visited the doctor three times every 2.5 weeks (Table No. 2).

Table 2. Case monitoring timetable for the patients per visit.

Evaluation of efficacy and safety variables was done in accordance with the observation schedule

STUDIES	Visit 1 (prior to starting therapy)	Visit 2 (after 2 weeks)	Visit 3 (after 4 weeks)
Informed consent	✘		
URTI frequency over the past 3 months, URTI frequency the previous year (December, January)	✘		
History of allergic reactions (presence of concurrent allergic conditions, ENT illnesses)	✘		
Patient examination	✘	✘	✘
Inclusion and exclusion criteria	✘		
Evaluation of URTI symptoms' intensity, should they occur (using a 5-point scale, where 0 means 'no symptom' and 4 means 'symptom has maximum intensity')	✘	daily	daily
ENT specialist consultation	✘		✘
Assessment of adverse events		✘	✘
General doctor and patient assessment		✘	✘

Results of the study and discussion:

Analysis of the observation cards has revealed that over the observation period, of the 43 children in the main group, individual intolerance of the drug was observed in three children (6%). All three had allergic conditions: bronchial asthma and perennial allergic rhinitis. In two patients, intensification of all URTI symptoms was observed, coupled with intensified bronchial asthma, which may have been connected with individual sensitivity. Nasal bleeding was noted in one patient on day four of using the drug. The drug was discontinued and the children were withdrawn from further observation. Thus, 40 children remained in the main group and continued to take the drug in accordance with the study protocol.

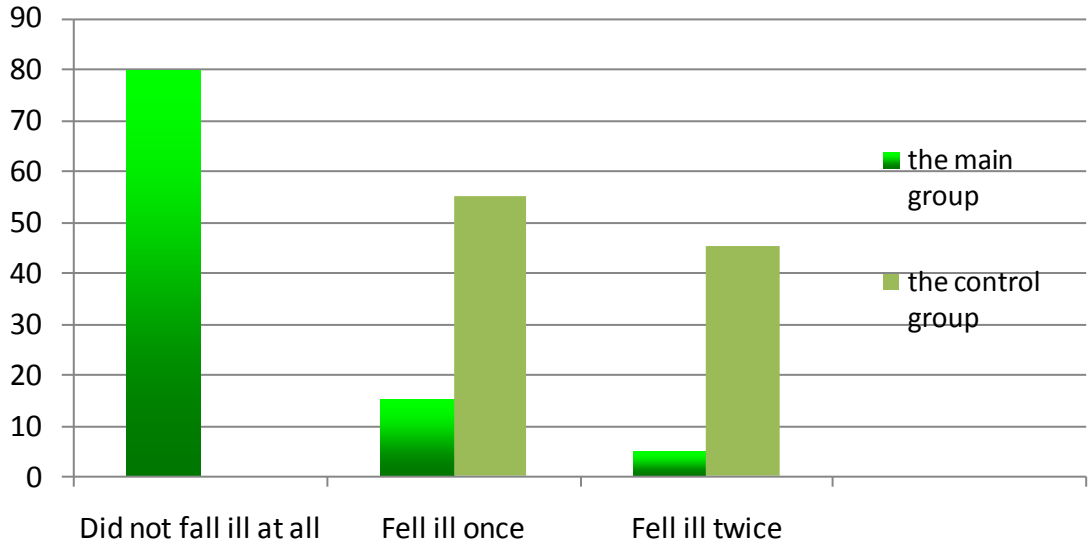
Of these 40 children:

- 32 children (80%) did not fall ill at all
- 6 children (15%) fell ill once
- 2 children (5%) fell ill twice

Table 3. Incidence of illness in children in the main and control groups for the observation period.

INCIDENCE OF ILLNESS	Nasaleze Cold	Control
Did not fall ill at all	32 *(80%)	0 (0%)
Fell ill once	6 (15%)	11 **(55%)
Fell ill twice	2 (5%)	9 *(45%)
TOTAL	40 (100%)	20 (100%)
* - differences are significant, (p<0.05)	** - differences are significant, (p<0.1)	

Fig. No. 1. Incidence of illness in children in the main and control groups for the observation period.



We have analysed the data about the incidence of illness among the children of the main group who received Nasaleze Cold for the same period the previous year. Table No. 2.

Table 4. Comparative analysis of incidence of URTI in 2008 and 2009 for children in the main group.

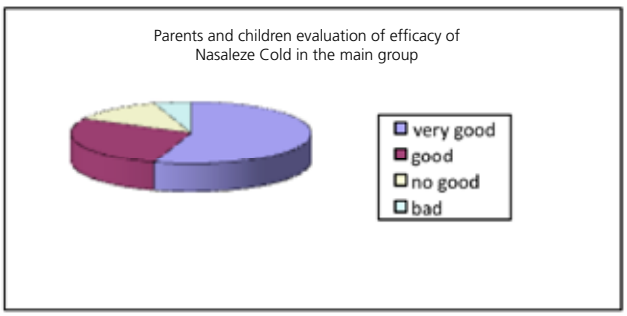
EVALUATION CRITERION	Number of children receiving Nasaleze Cold		
	2008 - 2009 (December, January, February)	2009 - 2010 (December, January, February)	
Number of instances of URTI	2.72 ± 1.11	0.25 ± 0.54	Decreased by 10 times
Duration of URTI (in days)	7.65 ± 3.54	3.24 ± 2.17	Decreased by 2.5 times

Thus, the number of children who did not fall ill in the main group was 80% (32 children); in 17.5% of children, the severity of illnesses decreased. Compared to the same period last year, taking Nasaleze Cold decreased incidence in 90% of patients.

Adverse effects associated with taking Nasaleze Cold were noted in four patients (10%). Five days after taking the drug, children experienced severe nasal discharge (rhinorrhea) and sneezing intensified; these decreased when antihistamines were added to the therapy. Three of these children had bronchial asthma coupled with perennial allergic rhinitis. One child had a medical history of chronic tonsillitis. These children had no catarrhal events registered over the whole observation period, their temperature did not go up, the children did not have URTI and continued taking Nasaleze Cold.

On the whole, the majority of parents (82.5%) and doctors (90%) considered the microdispersed cellulose powder Nasaleze Cold highly effective for the preventive treatment of acute respiratory infections **(Fig. No. 2, 3)**. Good tolerance of Nasaleze Cold was noted by 72.5% of parents and 87.5% of doctors **(Fig. No. 4, 5) .**

Fig. 2, 3. Parent and doctor evaluation of efficacy of Nasaleze Cold in the main group.



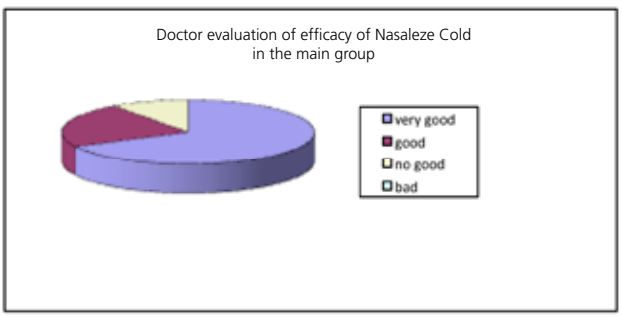
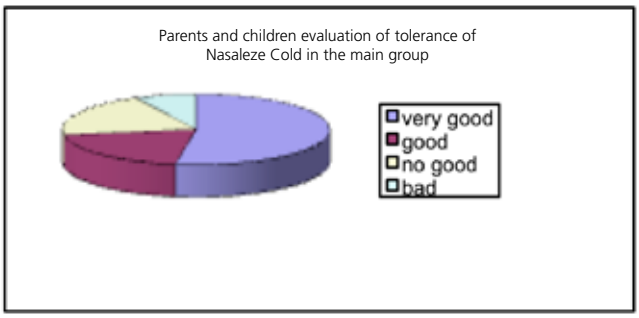
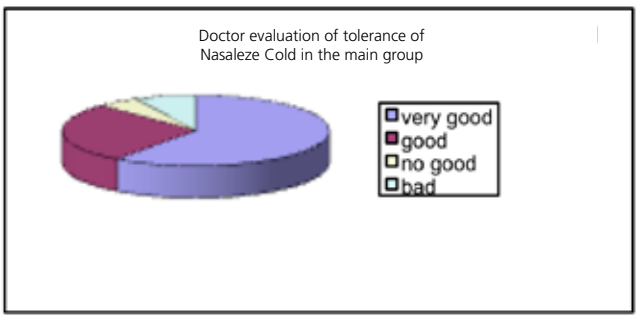


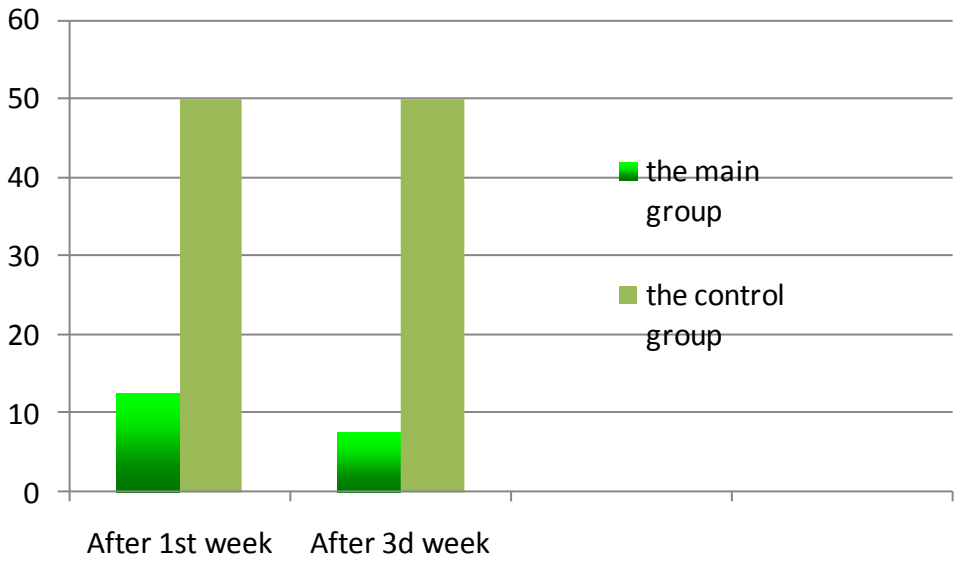
Fig. 4, 5. Parent and doctor evaluation of tolerance of Nasaleze Cold in the main group.





One week after the start of using microdispersed cellulose powder (Nasaleze Cold), five children (12.5%) had fallen ill in the main group, whereas 10 children (50%) had fallen ill in the control group. three weeks after starting use of the drug, in the main group three children – 7.5% (two of them had a repeat illness) fell ill in the main group, and in the control group, again 10 children fell ill – 50% (nine of them had a repeat illness). Fig. No. 6

Fig. No. 6. Illness incidence for children in the main and control groups towards the end of observation weeks one and three.



We have conducted a points-based evaluation of the URTI symptoms in children who fell ill in both groups, a week after the start of the URTI illness, i.e. weeks two and six after the start of observation. In two weeks, children in the main group who fell ill had a less marked manifestation of the main URTI symptoms, the points-based evaluation of which is shown in Fig. 1-7, as compared to the control group: nasal congestion in the daytime decreased from 0.91 ± 0.4 to 0.64 ± 0.6 points; nasal congestion at night decreased from 1.07 ± 0.5 to 0.67 ± 0.6; sneezing – from 0.62 ± 0.6 to 0.51 ± 0.6; headache, lack of energy and drowsiness decreased from 0.43 ± 0.5 to 0.25 ± 0.6; and restlessness during sleep decreased from 0.4 ± 0.5 to 0.23 ± 0.5 ($p<0.05$).

Dynamics of points-based evaluation of subjective URTI symptoms in children of the main and control groups in week two (visit two) and in week six (visit three) of the observation (OY axis – intensity of symptoms expressed in points) ($p<0.05$). Fig. No. 7-13.

Fig. 7. Nasal congestion in the daytime

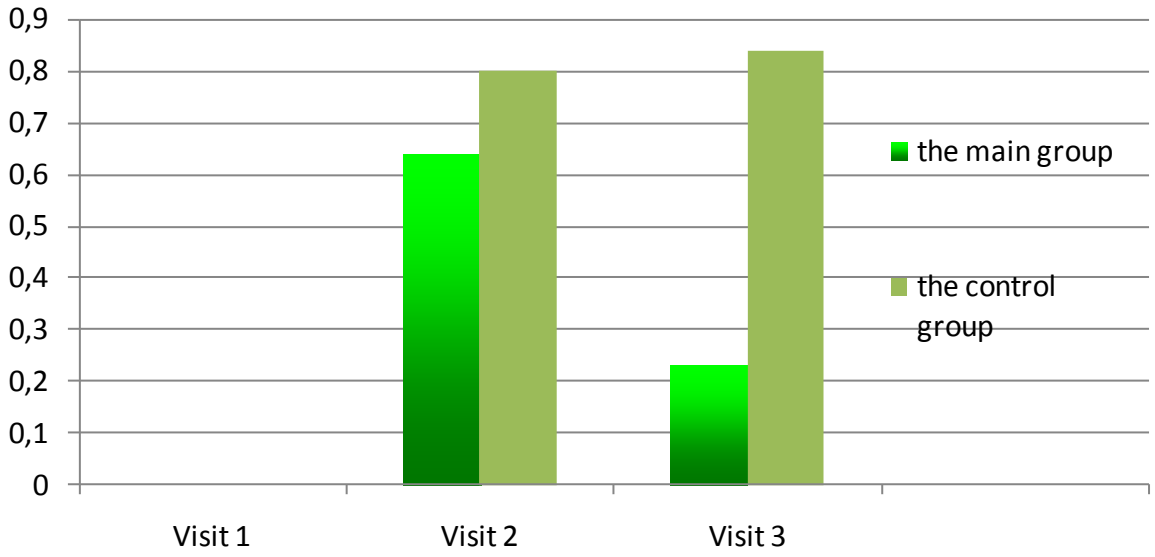


Fig. 8. Nasal congestion at night

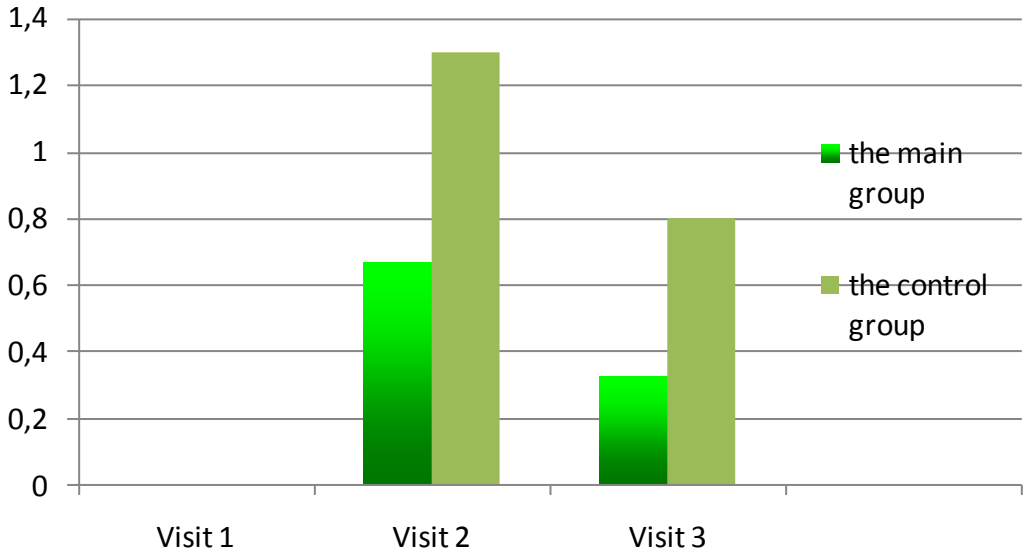


Fig. 9. Sneezing

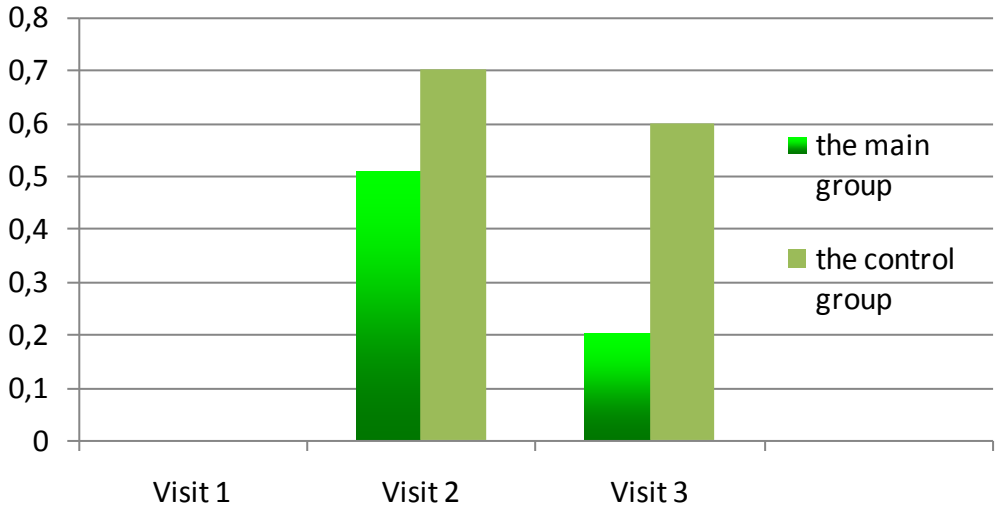


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Fig. 10. Nasal discharge

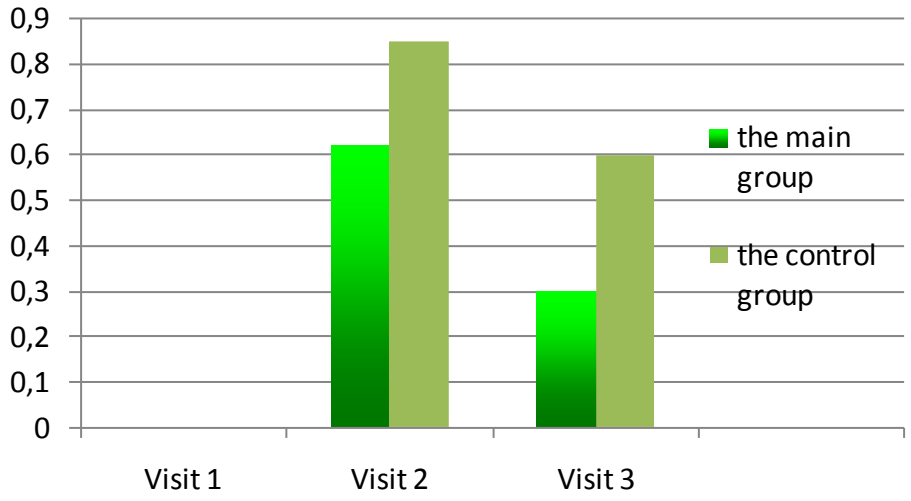


Fig. 11. Cough

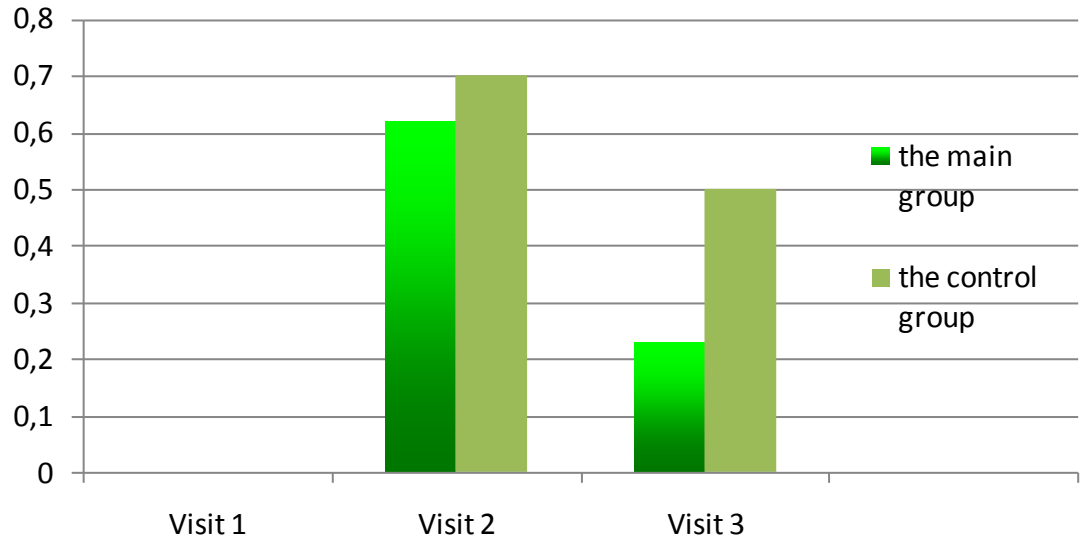


Fig. 12. Headache, lack of energy, drowsiness

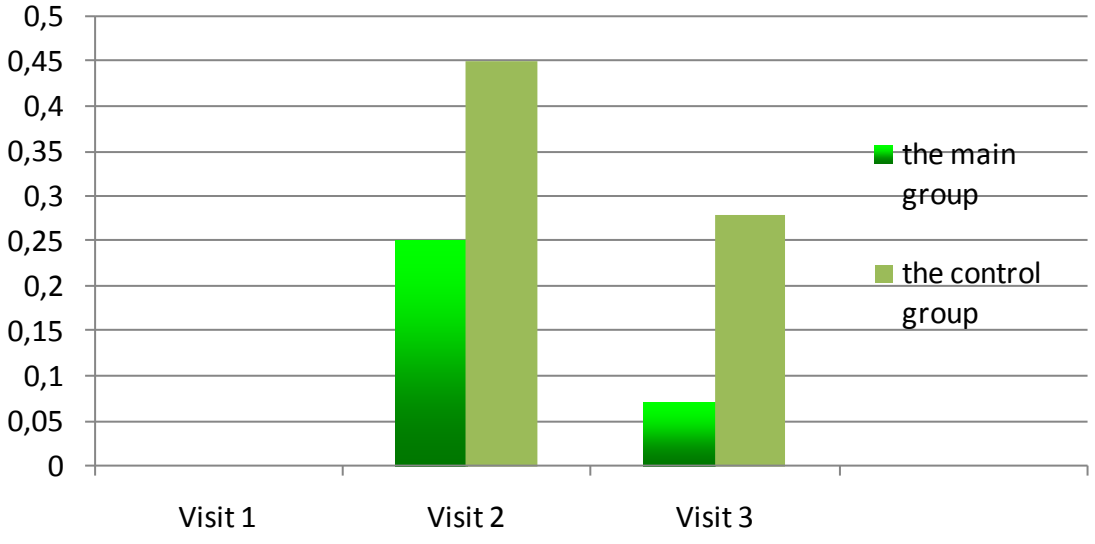
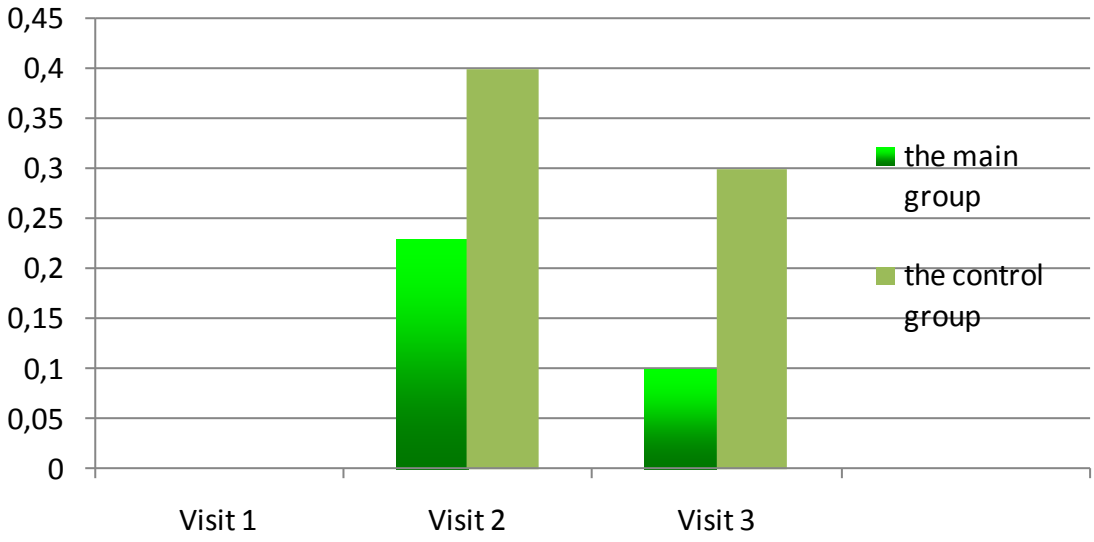


Fig. 13. Restlessness during sleep



In six weeks, a considerable reduction in objective and subjective URTI symptoms was noted as compared with the control group: nasal congestion in the daytime decreased from 0.91 ± 0.4 to 0.23 ± 0.37 points; nasal congestion at night - from 1.07 ± 0.5 to 0.33 ± 0.54; sneezing - from 0.62 ± 0.6 to 0.2 ± 0.44; nasal discharge - from 0.69 ± 0.5 to 0.3 ± 0.28; cough - from 0.64 ± 0.5 to 0.23 ± 0.4; headache, lack of energy and drowsiness - from 0.43 ± 0.5 to 0.07 ± 0.08; restlessness during sleep - from 0.4 ± 0.5 to 0.1 ± 0.09 ($p<0.001$). These data reflect the fact that fewer children had fallen ill by that time in the main group and their illnesses were less severe compared with those of the children in the control group.

Thus, the impact of the microdispersed cellulose powder Nasaleze Cold on objective and subjective URTI symptoms has been clearly demonstrated.

Conclusion:

1. When taking Nasaleze Cold:
   - did not fall ill during the observation period - 32 children (80%)
   - had one episode of URTI - six children (15%)
   - were ill twice - two children (5%).
2. Compared with the same period last year, the illness incidence decreased in 90% of patients, and the duration of URTI (in days) decreased by 2.5 times.
3. Whereas in the control group there were no children who did not fall ill at least once, 11 children (55%) fell ill once, and nine children fell ill twice (45%). Thus, the total number of children who fell ill in the main group is 80% less than in the control group.
4. Tolerance of the drug was noted as very good in the majority of cases; individual intolerance of the drug was observed in three children (6%). In two children, the start of taking the drug caused an intensification of bronchial asthma, of moderate to severe intensity, leading to withdrawal of the drug. In 1 patient, an instance of nasal bleeding was noted on day four of using the drug; this also led to withdrawal of the drug. Thus, Nasaleze Cold must be prescribed with care to children with moderate to severe bronchial asthma for the prevention of URTI. Moreover, presence of nasal bleeding in medical history should be a criterion for excluding patients from the study.

5. Many parents noted the ease of using the drug. The majority of parents (82.5%) rated the microdispersed cellulose powder Nasaleze Cold as a highly effective preventive agent against URTI. Good tolerance of the drug was noted by 72.5% of parents**.**

6. Also, when taking Nasaleze Cold, a clear effect on URTI symptoms in children who fell ill in the main group was noted as compared to control group children. A week from the start of illness, children experienced a definite reduction in such symptoms as nasal congestion in the daytime and at night, nasal discharge, cough, headache, lack of energy; and a tendency towards normal sleep was noted as compared to the control group. A definite reduction in objective and subjective URTI symptoms was also noted in week six of taking the drug.

7. Thus, the use of Nasaleze Cold as a means for preventing the development of respiratory illnesses in children must be recommended for a period of at least one month.

Nasaleze Cold can be recommended for carrying out preventive treatment of cold-related illnesses in children.

Discussion:

Thus, daily use of Nasaleze Cold with a preventive and protective aim: definitely prevents occurrence of respiratory infections (URTI); and protects against re-infection. Use of Nasaleze Cold during the active infection period helps to reduce the duration of the illness; and reduces the severity of URTI. It is important that Nasaleze Cold is not absorbed into the bloodstream, has no systemic action and does not affect immunity. It creates a double natural barrier, mechanical and biological, providing anti-bacterial and anti-viral protection. It is also known that Nasaleze Cold consists of only natural components and is safe for prolonged use throughout the season of cold-related diseases. Microdispersed cellulose powder is well-tolerated, easy to use and may be used in children of any age, starting from the very young. Regular use of inert cellulose powder in the nostrils may effectively prevent and alleviate the symptoms of URTI.

Nasaleze Cold is a modern, effective and safe natural spray for protecting the body against viruses, bacteria and other harmful external factors.

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