Intranasal Inert Cellulose Powder in Prevention and Management of Seasonal Allergic Rhinitis (SAR) in Children.

Geppe N.A., Snegotskaya M.N.; Kolosova N.G.; Konopelko, O.U. Conducted at the Clinic of Child Diseases at The I.M. Sechenov Moscow Medical Academy. An open comparative randomized study in order to evaluate the efficacy and safety of intranasal inert cellulose powder in preventing seasonal allergic rhinitis (SAR) in children.

The study was conducted between April and June 2009 and presented as a Poster in EACCI London 2010.

ALLERGY Nasaleze®
natural hayfever and allergy prevention

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Purpose:

To study the efficacy and safety of the intranasal inert cellulose powder (Nasaleze®) in the UK, Nasaval®) in Russia) to prevent seasonal exacerbation of allergic rhinitis (AR) in children. The Study was throughout 6 weeks between April and June 2009.

Materials and Methods:

Open randomized study in order to evaluate the efficacy and safety of the intranasal inert cellulose powder to prevent exacerbation of seasonal allergic rhinitis (AR) in children. Depending on the treatment all children were divided into the following groups: in Group 1 (Main Group), the inert cellulose powder in a special device was administrated to 30 children twice a day; in Group 2, 30 children received Montelukast 5 mg a day; in Group 3, 20 children received Sodium Cromoglicate 2 doses of 50 mg x 2 times a day; in Group 4, 30 children received Budesonide 50 mg 3-4 times a day. AR symptoms were assessed in the case monitoring timetable for the patients per visit. (Table 1.) Comparative description of the surveyed patients are in Table 2.

Table 1.

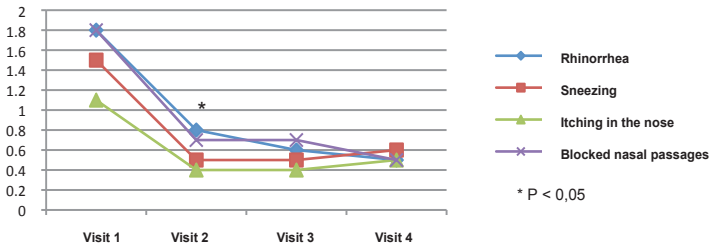
Study	Visit 1	Visit 2	Visit 3	Visit 4
Informed consent	X			
Questionnaire	X			
Collection of medical records	X			
Patient examination	X	X	X	X
Criteria for inclusion and exclusion	X			
Number Randomization	X			
Inert Cellulose Powder Issue	X			
Symptoms of seasonal allergic rhinitis (on a point scale: 0 - no symptoms, 1 - low level of intensity, 2 - moderate level of intensity, 3 - severe)	X	X	X	X
Treatment adjustment		X	X	X
Assessment of adverse events		X	X	X
General doctor and patient assessment		X	X	X

Table 2.

	Inert Cellulose Powder (N=30)	Montelukast (N=30)	Sodium cromoglicate (N=20)	Budesonide (N=30)
The average age of the patients (years)	8,3	8,9	7,9	8,5
Minimum age of the patients (years)	4,0	6,0	2 ,0	6,0
Average duration of the illness (years)	3,1	4	3,5	3,8
Sensitization to pollen allergens	50%	52%	49%	56%
Mild AR	22 (73,3%)	20 66,7%)	15 (75,5%)	20 (66,7%)
Moderate and severe AR	8 (26,6%)	10 (33,3%)	5 (25%)	10 (33,3%)
AR and BA	5 (16,7%)	8 (26,7%)	4 (20%)	9 (30%)
Allergic conjunctivitis	50%	53%	48%	57%
Family history of allergic illnesses	20 (66,7%)	22 (73,3%)	15 (75,5%)	20 (66,7%)

Results:

Dynamics of the symptoms of allergic rhinitis in scores within 6 weeks in Group 1 (the Inert Cellulose Powder).

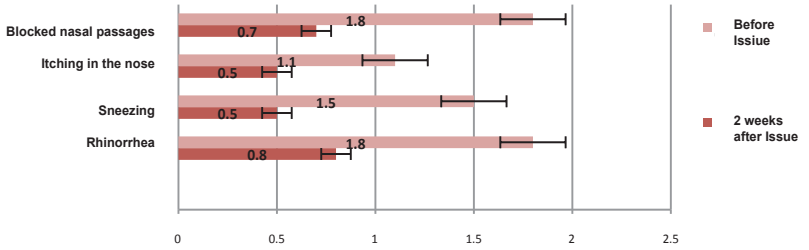


* P < 0,05

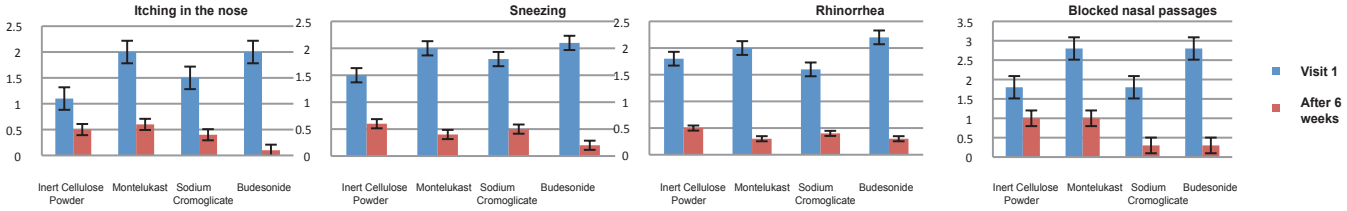
- The majority of patients (73%) noticed a distinct improvement in their condition by the fifth day.
- During the next 2 weeks, 12 children's (40%) symptoms disappeared completely.

Evaluating the efficacy of the Inert Cellulose Powder in children with AR during the first two weeks (p<0,05)

- Definite decrease of all SAR symptoms more than twice.
- 75% of patients before the prescription regularly received decongestants. During the Study 26,9% of patients occasionally received decongestants.



Efficacy of the Inert Cellulose Powder in children with seasonal symptoms AR within 6 weeks compared with other variants of treatment.



In the Main Group (Group 1) 9 children (34,6%) were receiving antihistamines occasionally, 7 children (26,9%) - decongestants, 3 children (10%) – nasal topical steroids. Comparing showed a significant improvement in symptoms of AR in all groups.

Side effects: 2 children (6,7%) in the Group 1 had increased sneezing, followed by removal of the drug. In the Budesonide group, two children was a slight nasal bleeding and burning of the nasal mucosa (6,7%).

Conclusion: The Inert Cellulose Powder reduces symptoms of AR, as well as other medicines. The children who received the Inert Cellulose Powder during pollen season, decreased frequency of use of antihistamines, decongestants and topical steroids. Preventative application of the Inert Cellulose Powder before contact with known allergens (pets, pollen allergens, house dust, etc.) reduces the symptoms of allergy. Using of the Inert Cellulose Powder for prevention of seasonal allergic rhinitis was proved. The Inert Cellulose Powder has minimal side effects and can be used in children from an early age.