

# Clincial Studies Summary



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# Study 1: AIVAZIA - 2005

Aivazis V, Bourli E, Maratou E, Mavroudi A, Aivazi D, Foutzila E and Ilonidis G.

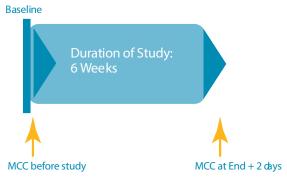
Study of mucociliary clearance in children with allergic rhinitis, before and after a six week therapy with natural cellulose powder.

Nea Pediatrica Chronica. 2005; 5(2)

## **Objective**

To determine the nasal mucociliary clearance\* rate before and after monotherapy with natural cellulose administrated in the form of inhaled powder in children with allergic rhinitis.

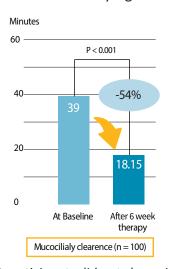
## Design



Mucociliary clearance (MCC) was determined in vivo by means of a non-invasive ye method\*\*

#### Results

The MCC was reduced from 39 minutes to 18.15 minutes – a statistically sign can't reduction.



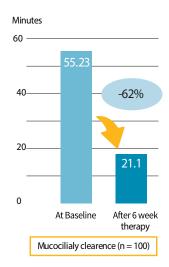
## **Population**

100 Children: 53 boys and 47 girls,

Mean age of the study group = 7.95 years (range 1.5 – 8 years)

All children had a positive medical history for allergic rhinitis.

51% of the participants who had abnormally prolonged clearance (55.23 minutes) at the beginning of the trial reached a normal MCC (21.1 minutes) after treatment with Alzair™.



Only 5 participants did not show significant improvement.

#### Conclusion

The significant decrease of MCC observed in participants is due to Alzair<sup>™</sup>, as the participants received no other therapy. Alzair<sup>™</sup> enhances natural defenses by improving the function of the nasal mucus. Effective filtration of allergens helps to ensure only fresh air reaches the lungs.

<sup>\*</sup>Mucociliary clearance is an upper airway defense mechanism. Measuring the MCC provides a quantifiable measurement of cilial function and how diseases such as allergic inflammation can affect the mucociliary system.

<sup>\*\*</sup>Dye Test: the dye (Edicol Orange 3% + CaHPO4 2H2O 97%) marks the infiltration area and the time it takes for its reappearance is recorded.



# Study 2: DIETHART - 2010 (A)

Diethart B, Emberlin J. C, Lewis R. A.

Hydroxypropyl methylcellulose (Alzair™) gel application delays Der p1 diffusion in vitro.

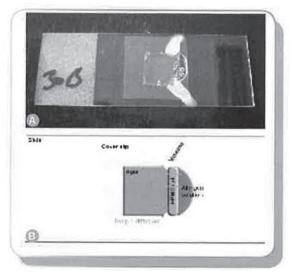
Natural Science. 2010; 2(2): p79-84

## **Objective**

To investigate whether the HPMC gel acts as a mechanical barrier to Der p1 and prevents allergen diffusion towards the nasal epithelium.

## Design

ELISA\* was used to determine the amount of Der p1 which diffused through the cellulose gel and agar gel (imitation of nasal mucosa) in vitro.



Photograph (A) and diagram (B) of experimental setup for sample preparation for ELISA measurements of Derp 1 diffusion through HPMC gel.

Measurements were conducted at 15, 30, 45, 60, 180 and 360 minutes after application of the standard allergen solution.

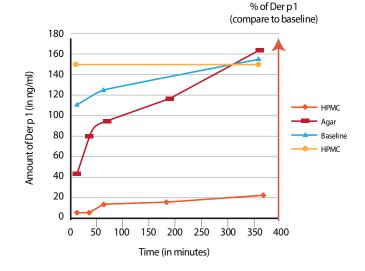
Results were compared to baseline reading (control) without a gel layer.

## **Results**

Alzair™ significantly reduced the amount of diffused allergens in all tests.

After 15 minutes, only 0.76% had diffused through the cellulose gel compared to the 28.1% of allergens which had diffused through the agar gel.

After 360 minutes the cellulose gel had only allowed 14.1% of the baseline allergens through while the agar gel had let 100%.



#### **Conclusion**

Alzair™ significantly delays Der p1 diffusion in vitro compared to both no barrier and the agar gel.

Alzair™ creates a polymer network with a small mesh size which inhibits the allergens diffusion to the nasal epithelium.

<sup>\*</sup>ELISA (Enzyme-linked immunosorbent assay): an enzyme immunoassay which detects specific antigens in a wet sample.



# Study 3: DIETHART - 2010 (B)

Diethart B, Emberlin J. C, Lewis R. A.

Nasal mucociliary clearance and mucoadhesion of hydroxypropyl methylcellulose powder used for alleviation of allergic rhinitis.

Poster presented at EAACI, 2010.

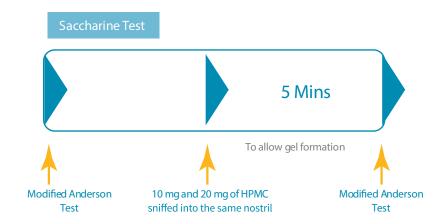
## **Objective**

To investigate the effect of Alzair™ on mucociliary clearance in healthy participants.

## Design

For this investigation, a modified Andersen saccharine test was applied.

Modified Andersen Saccharine Test\*: saccharine solution applied to interior of one nostril, participants were instructed not to sniff or sneeze and to report sweet taste. Time is measured from administration of saccharine solution to the sweet taste being detected.



Saccharine test (for mucociliary clearance): The upper respiratory tract is cleaned and small crystals of saccharin are placed on the inferior nasal mucosa. The time is measured until the patient has a sweet taste in the mouth. With normal ciliary transport the time should be 30 mins or less.

## **Population**

12 healthy volunteers.

|   | Women     | Men       |
|---|-----------|-----------|
| Number of participants                  | 9         | 3         |
| Mean age (in years)                     | 32.8      | 37        |
| Age range (in years)                    | 25-40     | 25-60     |
| Allergic rhinitis during last two years | 3 (33.3%) | 1 (33.3%) |
| Smokers                                 | 1         | 1         |

# Study 3: DIETHART - 2010 (B) continued

## **Results**

The mean mucociliary clearance time at baseline = 11.14 minutes.

Mean MCC with 10mg of HPMC = 35.45 minutes.

Mean MCC with 20mg of HPMC = 50.37 minutes.

Mean MCC with 20mg was statistically sign can't when compared to baseline and 10mg HPMC.

MCC with 20mg was 420% times longer than the baseline.

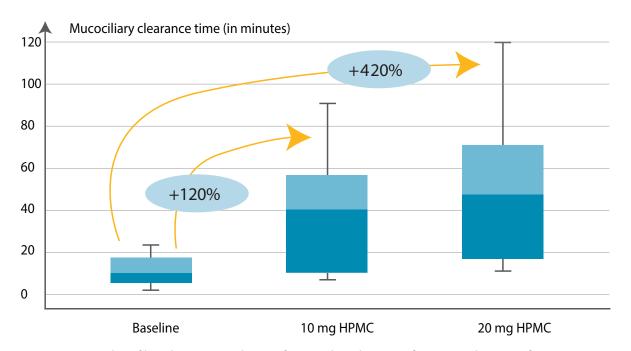


FIG 1: Boxplot of baseline MCT and MCT after nasal application of 10 mg and 20 mg of HPMC (n = 12, p < 0.0005)

#### Conclusion

The attachment of HPMC to nasal mucus (mucoadhesion) creates a barrier stopping allergy entry – this is demonstrated by the increase of MCC.

The increase in MCC demonstrates that the attachment of Alzair™ to the nasal mucus (mucoadhesion) creates a mechanical barrier stopping allergy entry.

Mucoadhesion also slows down nasal clearance, enabling longer residence time of Alzair™ in the nasal cavity. Alzair™ can now be an effective barrier for longer before it is cleared.

HPMC gel increase mucus viscosity, which might decrease the diffusion coefficient resulting in lower allergen diffusion.

<sup>\*</sup>Saccharine Test: The upper respiratory tract is cleaned before small crystals of saccharin are placed on the nasal mucosa. The time taken for the patient to taste a sweet sensation is recorded. Normally it should take 30 minutes for the sweet taste to be detected.



Josling P, Steadman S.

## Use of Cellulose Powder for the Treatment of Seasonal Allergic Rhinitis.

Advances in Therapy. 2003; 20(4): p213-219

## **Objective**

To determine whether Alzair would be able to prevent an allergic rhinitis attack from occurring in participants who have suffered for many years.

## **Design**





#### **Pretrial questionnaire**

5-point scoring system to grade general well-being and severity of any hay fever attacks.

Daily questionnaire was conducted assessing general well-being of the participant (5=well, 1=full hay fever attack). Number and variety of symptoms were listed along with day or time elapsed when recovery began and time until symptoms were resolved.

## **Population**

102 volunteers:

66 female, 36 male. Mean age = 44 years old. All participants had previously used products for seasonal allergic rhinitis.

| Treatment   | Male<br>Volunteers | Female<br>Volunteers |
|---|--------------------|----------------------|
| Beconase® (steroid nasal inhaler) Glaxo Smith Kline, UK                           | 3.0                | 3.1                  |
| Sodium cromoglycate (antihistamine nasal inhaler) - various generic manufacturers | 1.3                | 2.1                  |
| Opticrom® (eyedrops) Aventis Pharma, UK   | 1.5                | 2.0                  |
| Clarityn® (oral tablets) Schering Plough, UK                                      | 2.0                | 2.2                  |
| Zirtech® (oral tablets) Glaxo Smith Kline, UK                                     | 1.1                | 1.8                  |
| Piriton® (oral tablets and liquid) Stafford Miller, UK                            | 1.3                | 1.8                  |
| Telfast® (oral caplet) HMR, UK  | 2.0                | 1.8                  |
| Alzair  | 3.8                | 3.9                  |

## Study 4: JOSLING - 2003 continued

## Alzair™

On average the daily score with the Alzair™ treatment was over 4.0 in 35% of participants and above 3.0 (an occasional sneeze but no hay fever symptoms) in over 70% of participants. After six weeks of using Alzair 70% participants rated the product as good or excellent.

| Volunteers | Good | Excellent |
|------------|------|-----------|
| Male       | 76   | 69        |
| Female     | 80   | 75        |
| TOTAL      | 78   | 72        |

Only 12% of participants had an average daily score of less than 2.9.

Participants were statistically likely to gain relief from symptoms within 0.1 to 3 hours of using Alzair™.

## **Conclusion**

Alzair<sup>™</sup> relieved classic hay fever symptoms, sometimes within minutes but often within 3 hours of inhalation. Previous drug treatment had never alleviated patient's hay fever symptoms whereas upon treatment with Alzair<sup>™</sup> there was resolution of symptoms.

Alzair™ treatment should be started as early as possible and continued throughout the pollen season, with number of applications increasing as appropriate to the individual.

<sup>\*6</sup> women and 2 men required additional treatment with pharmaceutical products, however volunteers who took more than the recommended amount often perceived increased relief in their symptoms.\*

# Study 5: VLAHTSIS - 2004

#### Vlahtsis K.

Clinical study of Alzair™ for relief of allergy symptoms including sneezing, runny nose, itchy and watery eyes.

Poster presented at Pan-Hellenic Conference of ENT Specialists, March 2004

## **Objective**

To study how Alzair™ can benefit perennial or chronic allergy sufferers and protect from allergens such as dust mites, pet dander and smoke.

## Design

One application of Alzair™ per nostril, mainly in the morning or shortly before the known time of day when symptoms usually appear. Duration of trial was 6 weeks with evaluations at time 0, 3 weeks and 6 weeks.

## Scale used to measure symptoms (sneezing, runny nose, itchy and watery eyes):

5 = complete relief, without symptoms

4 = major relief, casual sneezing

3 = light, but noticeable allergy symptoms

2 = allergy symptoms apparent with periodic flare ups

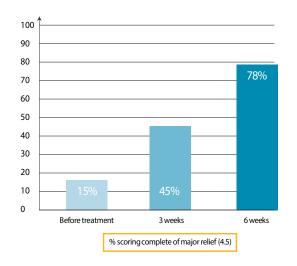
#### **Population**

40 participants (24 women and 16 men).

All participants suffered from diagnosed allergic rhinitis diagnosed by radioallergosorbent test (RAST). Previously used a pharmaceutical treatment either over-the-counter or prescribed.

#### **Results**

After three weeks of use, 85% of participants realized improvement in their allergy symptoms. This number increased to 90% after 6 weeks.



**Table 1**78% have complete or major relief from symptoms after 6 weeks.

|         | 3 SCALE<br>IMPROVEMENT | 2 SCALE<br>IMPROVEMENT | 1 SCALE<br>IMPR OVEMENT | 0 SCALE<br>IMPROVEMENT | MEAN<br>IMPROVEMENT |
|---------|------------------------|------------------------|-------------------------|------------------------|---------------------|
|         | 0%                     | 5%                     | 80%                     | 15%                    | 0.9 scales          |
| 6 weeks | 7.5%                   | 35%                    | 47.5%                   | 10%                    | 1.4 scales          |

There were no side effects reported by any of the participants. Participants reported that the product was simple and easy to use.

#### Conclusion

Alzair™ is able to decrease symptoms for participants who suffer from non-pollen induced allergic rhinitis.



# Study 6: EMBERLIN - 2006 (A)

Emberlin J, Lewis R.

A double blind, placebo controlled trial of inert cellulose powder for the relief of symptoms of hay fever in adults.

Current Medical Research and Opinion. 2006; 22(2): p275-285

## **Objective**

Principle Aim: to determine if there is a significant difference in the amount and type of rescue medication required for adult hay fever sufferers to control their symptoms.

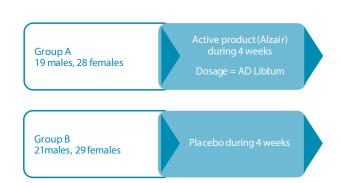
Secondary Aim: to determine whether the cellulose powder resulted in an improvement in symptom control.

## Design

Double blind, randomized, placebo controlled study.

Participants were required to fill out daily diary cards for 4 weeks. The card include requests for:

- Likert scores for the following over the last 24hr: sneezing, runny nose, blocked nose, watering eyes
- How many times Alzair was used that day
- If any other allergic rhinitis medication or treatment was taken that day and if so what type and how much.
- Visit to GP or nursed related to their allergy rhinitis
- Whether they had cold or flu like symptoms. If so what were these?

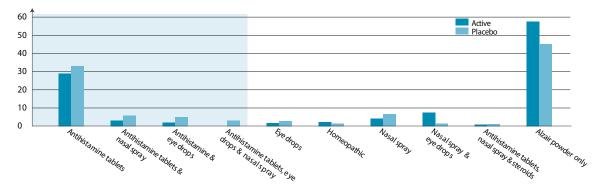


#### **Population**

The 97 participants who participated in the study were divided into two groups (A – active, B – placebo) matched by age by decades and gender. All patients had symptoms of seasonal allergic rhinitis during June and July (grass pollen season) for at least 2 years.

#### **Results**

Significant differences were found in the overall amounts of rescue medication taken by the active and placebo groups. The placebo group took more rescue medication than the active group.



A significant difference was detected between the active and placebo group for the symptoms; running nose and blocked nose. 57% of participants in the active group only took Alzair™ with no rescue medicine compared with 44% in the placebo group. No adverse effect were reported during the study.

#### Conclusion

This trial demonstrates that Alzair<sup>™</sup> significantly reduced the need to take rescue medication for allergic rhinitis. Alzair<sup>™</sup> has a positive effect on reducing common symptoms of allergic rhinitis such as runny and blocked nose.

Emberlin J, Lewis R.

A double blind, placebo controlled cross-over trial of inert cellulose powder, by nasal provocation with grass pollen to assess efficacy of the product in controlling symptoms of hay fever.

Poster presented at EAACI, 2006

## **Objective**

To explore the effects of Alzair™ in controlling symptoms when subjects are not taking any other medication.

## Design

Double blind, placebo controlled, cross over trial.

After the powder (real or placebo) was placed in the nose, the equivalent of 350 grains per cubic meter air of grass pollen was placed in the nose.

Scores were taken for 6 symptom categories; nasal secretions were sampled for ECP\* and nasal peak inspiratory (PIF) and expiratory flow (PEF) were measured at regular intervals for 4.5 hours.

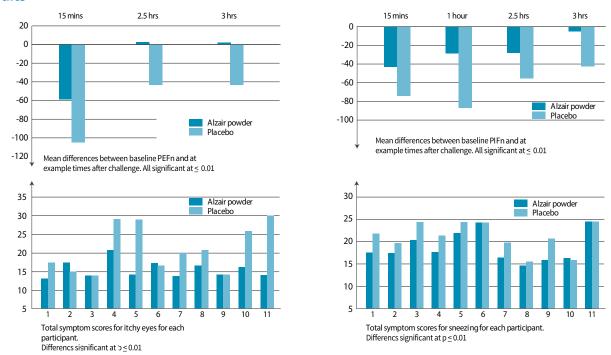
## **Population**

11 adults

All participants were diagnosed as allergic to grass pollen but not to tree pollen by SPT.

All participants had suffered from symptoms in the two previous summers.

#### **Results**



A significant reduction was found in nasal secretions and therefore ECP.

Results for other lung function tests and symptoms were slightly under the level of significance.

No adverse effect recorded.

#### **Conclusion**

Alzair<sup>™</sup> has a significant effect in reducing the symptoms (sneezing and itchy eyes) of a grass pollen allergy.

Alzair<sup>™</sup> also has a significant effect in reducing nasal inflammation, as shown with the reduction in nasal PEF, PIF and ECP. Alzair<sup>™</sup> is an effective treatment for allergic rhinitis due to its ability to alleviate symptoms.

<sup>\*</sup>Eosinophil Cationic Protein (ECP) are released from the eosinophil upon activation. They are attracted to the site of inflammation and become activated where they secrete several tissue-toxic mediators.



# Study 8: EMBERLIN - 2007

Emberlin JC, Lewis RA.

Double blind placebo controlled cross-over trial of Alzair™ by nasal-provocation tests with Der p1 and Der f1.

Current Medical Research Opinion. 2007; 23(10): p2423-2431

#### **Objective**

To assess whether Alzair™ would reduce the response to nasal challenge with house dust mite allergens.

## Design

Double blind, placebo controlled, cross over trial.



Pre-Wash - 15 min

Crossover at least 7 days after the 1st visit (wash out)

Severity scores of symptoms (sneezing, nasal secretion, runny eyes, level ECP, nasal blockage, itching of the nose, throat and eye, PIF and PEF) were taken at regular intervals: 5 minutes after the challenge, every 15 minutes for the first hour after the challenge, then 30 minutes' intervals until 4 hour, then at 6h and at 24h.

Symptoms were scored using the system below:

0 = absent.

- 1 = very mild, symptoms hardly noticeable.
- 2 = mild, symptoms noticeable all the time but do not interfere with any normal daily activities.
- 3 = moderate, symptoms noticeable all the time but do not interfere with any normal daily activities.
- 4 = severe, symptoms interfere with normal daily activities some of the time.
- 5 = very severe, symptoms interfere with normal everyday activities constantly.

Nasal secretions were sampled for ECPS and measures were taken of PIF and PEF at 5 minutes after challenge, 15 minutes later, then at 30 minute intervals for 2 hours and then again at 4 hours.

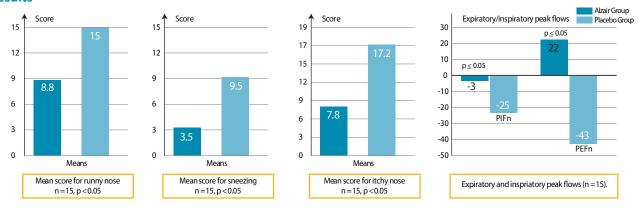
#### **Population**

15 adults (7 female and 8 male)

All persistent rhinitis sufferers – diagnosed positive to Der p1 and/or Der f1 by SPT.

All had symptoms for the previous two years.

#### **Results**



There were no adverse reactions.

#### **Conclusion**

Alzair™ can have significant effects in reducing some symptoms of persistent rhinitis due to house dust mite allergy.



# Study 9: ZAKHARZHEVSKAYA -2009

Zakharzhevskaya TV, Sidorenko IV, Treskunov VK, Karaulov AV.

Efficacy and safety of medical device Alzair™ in prevention and treatment of persistent allergic rhinitis in adults and children.

Study presented at Moscow XVI Congress for Man and Drugs, 2009

#### **Objective**

To investigate the effectiveness and safety of Alzair™ as a medical device in prevention and treatment of allergic rhinitis.

## Design

Participants received one puff of Alzair™ into each nostril 3 times a day for 4 weeks.

Once a week the participant would visit an investigator and their AR symptoms and the tolerability of Alzair $^{\text{TM}}$  was assessed. A quality of life questionnaire and a visual analogue was filled out during initial and final visits. All symptoms (sneezing, nasal and nasopharyngeal itching eyelid itching, nasal discharge, and impaired nasal breathing) were assessed using this following scale 0 = no symptoms to 5 = severe symptoms.

The effectiveness of treatment was assessed by investigator together with the patient during the final visit. A daily diary was kept by all participants to record the severity of AR symptoms, any side effects and need for other medication.

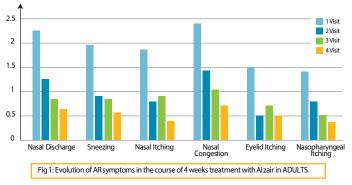
#### **Results**

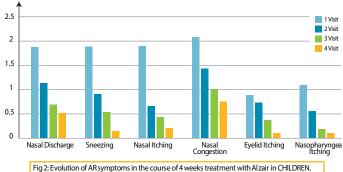
Improvement of AR symptoms was detected after just 1 week of treatment with Alzair $^{\text{TM}}$  and a significant decrease in the severity of all symptoms was detected by the end of the 4 weeks.

## **Population**

48 patients: 25 adults and 23 children of both genders. Age range 2-62 years old.

All had persistent allergic rhinitis.



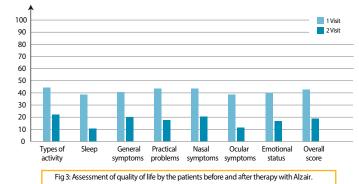


The majority of both adults and children assessed the efficacy of the product as good or very good. Only 2% of participants found Alzair<sup>™</sup> moderately effect and none found it ineffective.

Assessment of the efficacy of Alzair™.

| EFFECTIVENE SS | ADULTS (% OF ALL<br>ADULT SUBJECTS | CHILDREN (% OF ALL<br>PEDIATRIC SUBJECTS | TOTAL (% OF ALL<br>SUBJE CTS |
|----------------|------------------------------------|--|------------------------------|
| Very good      | 45                                 | 38                                       | 41                           |
| Good           | 50                                 | 62                                       | 57                           |
| Moderate       | 5                                  | -  | 2                            |
| No effect      | -                                  | -  | -                            |

Both children and adults reported good or very good tolerability of Alzair $^{\text{\tiny{TM}}}$ .



#### **Conclusion**

After one week of treatment Alzair™ reduces the severity of AR symptoms.

A two-fold improvement in the quality of life of the participants was reported after 4 weeks of treatment with Alzair™ is capable of creating a natural safe barrier protecting the airways from contact with allergens and oxidizing pollutants.



# Study 10: ILINA - 2011

Ilina NI.

Open non-comparative study to evaluate the effectiveness of Alzair™ for patients with allergic rhinitis.

Russian Allergy Journal, 2011.

## **Objective**

To evaluate the effectiveness of Alzair<sup>™</sup> for patients with allergic rhinitis.

#### Design

Prospective open non-comparative study.



Nasal provocation tests increased until a positive reaction occurred.

## **Population**

30 participants (18 women and 12 men) with an age range of 18 to 65 years old (mean age = 28.5).

Positive skin tests for dust and household or epidermal allergens. Suffered from allergic rhinitis for no less than 2 years.

#### **Results**

28 out of the 30 participants found Alzair™ to be an effective therapy.

Nasal reactivity was shown to significantly decrease after treatment with Alzair™.

The concentration of allergen needed to cause an allergic reaction increased from 1250 PNU/ml with no treatment to 5000 PNU/ml with Alzair™.

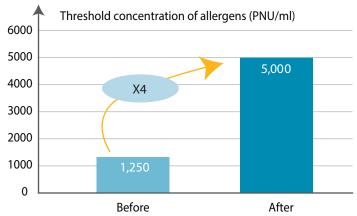


Fig 1: Threshold concentration of allergens (n + 30).

## **Conclusion**

Under conditions of allergen provocation, Alzair™ has a prophylactic action and prevents the development of an allergic reaction. For Alzair™ to be effective it must be applied before coming into contact with allergens and throughout the contact period. Alzair™ has a high degree of safety due to the natural cellulose powder and has no systemic action in connection with the above, Alzair™ can be used by children and by pregnant or breast-feeding women.



# Study 11: ABERG - 2011

Aberg N, Benson M.

A nasally applied cellulose powder in Seasonal Allergic Rhinitis (SAR) in children and adolescents; reduction of symptoms and relation to pollen load.

Pediatric Allergy and Immunology. 2011; 22(6): p594-599

## **Objective**

To assess the efficacy of Alzair™ in a common clinical setting along with an oral histamine in treating seasonal allergic rhinitis in children.

## Design

A double blind, placebo-controlled study.

Duration of study = 4 weeks

ACTIVE TREATMENT 3 X/DAY:
Alzair 3X/DAY + DESLORATADINE (1 TABLE T/DAY)

PLACEBO TREATMENT 3 X/DAY + DESLORATADINE (1 TABLET/DAY)

SMS was used to provide instructions, reminders and reporting of symptoms.

At the end of each day participants were asked to report the severity of their symptoms (sneezing, runny nose, blocked nose, eyes and lower airways) using the scale below:

- 1 No trouble at all
- 2 Little trouble
- 3 Moderate trouble
- 4 Rather much trouble
- 5 Much trouble
- 6 Very much trouble

All reminder and reports were done using SMS on mobile phones.

#### Results

General tendency for reduction in symptom scores for all symptoms in the active group.

There was a significant reduction for sum of nasal symptoms and specifically running nose.

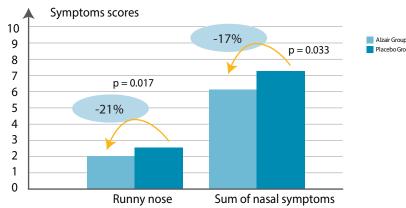
With a low to moderate pollen count sneezing is also significantly reduced.

**Population** 

53 children participated in the study (age range 8-18 years old)

Must have tested positive for birch pollen allergy through a skin prick test.

They should not have used nasal steroids.



Reduction of nasal symptoms

#### **Conclusion**

Alzair™ causes a significant alleviation of nasal symptoms in SAR in children and adolescents specifically runny nose and sneezing. The best efficacy was seen after a low-moderate birch pollen load.

Alzair™ is effective in combination with oral antihistamine, the most common treatment of SAR.

# 12 Study 12: ABERG - 2014 (B)

Aberg N, Ospanova ST, Nikitin NP, Emberlin J, Dahl A.

A nasally applied cellulose powder in seasonal allergic rhinitis in adults with grass pollen allergy:

A double-blind, randomized, placebo-controlled, parallel-group study.

International Archives of Allergy and Immunology. 2014; 163(1): p 313-318

## **Objective**

To assess the efficacy of Alzair™ in grass pollen rhinitis in adults in Europe.

## Design

A double-blind, placebo-controlled study.

Patients were randomly assigned to the placebo or active group.

Patients had to puff the powder 3 times daily for 4 weeks.

Reminders were sent out by SMS to patients and SMS confirmation of powder application was sent back to the researchers.

In the evening, the severity of the patient's symptoms (nose: sneezing, running nose and blocked nose, eyes and lower airways) were scored from 1 (no symptoms) to 6 (strong symptoms).

The use of rescue medication was also recorded.

## **Population**

108 patients, age range: 18-40 years old.

A positive test for timothy grass pollen was required for inclusion.

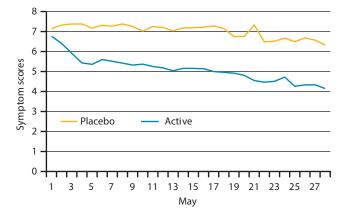
#### Results

A significant reduction was detected in the severity scores for sneezing, runny nose, stuffy nose and symptoms from eyes and lower airways, both separately and together.

87.1% of the active participants found the product had a good effect.

| OPINI ON         | PLACEBO, N | ACTIVE, N  |
|------------------|------------|------------|
| No effect        | 28 (52.8%) | 4 (7.4%)   |
| Good effect      | 12 (22.6%) | 32 (59.3%) |
| Very good effect | 1 (1.9%)   | 15 (27.8%) |
| Don't know       | 12 (22.6%) | 3 (5.6%)   |

Group differences, p < 0.001.



Only one patient in the active group received rescue medication – antihistamine tablets.

#### **Conclusion**

Alzair™ provided significant protection against all seasonal allergic rhinitis symptoms.

The magnitude and scope of efficacy support using Alzair™ as a preventative measure for allergic rhinitis.



# Study 13: VALERIEVA - 2015

Valerieva A, Popov TA, Staevska M, Kralimarkova T, Petkova E, Mustakov T, Lazarova T, Dimitrov V, and Church M.

Effect of micronized cellulose powder on the efficacy of topical oxymetazoline in allergic rhinitis.

Allergy Asthma Proceedings. 2015; 36(1): p1-6

## **Objective**

To assess the ability of Alzair™ to prolong and enhance the effectiveness of pharmaceutical therapies in the nasal cavity.

## Design

Double-blind placebo-controlled study.

Peak inspiratory nasal flow was measured for 360 minutes after oxymetazoline and HPMC or placebo application on days 1 and 8 and at a single point on day 15.

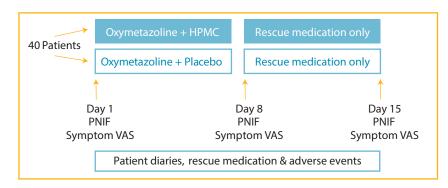


Figure 1. Study protocol

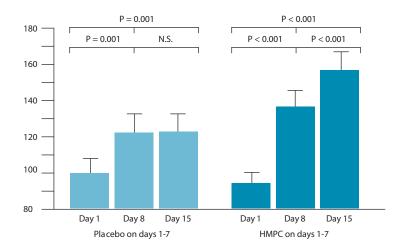
## **Population**

40 participants (23 women and 17 men) with a mean age of 35 years old.

All had a clinical history of persistent moderate-to-severe allergic rhinitis and a positive skin prick diagnosis.

#### Results

Alzair™ significantly enhanced oxymetazoline, PNIF was higher at day 1 and 8.



Baseline PNIF values at days 1, 8, and 15. Each group contains results from 18 individuals. Significance values were calculated by using the student's t-test for paired data. \*The baseline PNIF of the patients treated with HMPC at 15 days was significantly (p = 0.014) higher than that of patients treated with placebo. This value was calculated by using the Student's t-test for unpaired date.

Alzair™ reduces nasal congestion as PNIF is greater in the Alzair™ group than in the placebo.

By day 8 both groups had relieved nasal symptoms but only the active group continued to see improvements until day 15. The active group used less rescue medication than the placebo group between days 8 and 15.

#### **Conclusion**

Alzair™ enhances the decongestant effect of oxymetazoline in allergic rhinitis patients.

The carryover efficacy of oxymetazoline for a week after its discontinuation may be due to Alzair™ aiding the mucosal barrier.