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ORIGINAL ARTICLE

Pollen challenge study of a phototherapy device for reducing the symptoms of hay fever

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Key words: **Hay fever – Grass pollen – Phototherapy – Provocation test**

ABSTRACT

Objective: The objective was to investigate the effect of intranasal phototherapy delivered by a phototherapy device (allergy reliever SN-206) on symptoms of hay fever (seasonal rhinitis) due to grass pollen in adults. This registered class IIA medical device had been on sale for 15 months with no adverse effects reported but there had been no assessment of efficacy. Previous research had indicated that phototherapy could alleviate symptoms of allergic rhinitis but no double-blind, placebo-controlled trails had been done.

Research design and methods: The trial is a double-blind, placebo-controlled grass pollen challenge conducted out of the pollen season, on 101 adult male and female hay fever sufferers. Subjects were assigned to placebo or active groups by stratified random sampling using responses to a baseline questionnaire. All subjects used active or placebo devices three times a day for 14 days before pollen challenge. Subjects were monitored for 2.5 h after challenge.

Main outcome measures: Primary outcome measures were observed severity scores for sneezing, running eyes, running nose, and the amount of eosinophil cationic proteins (ECP) in nasal secretions. Secondary outcome measures were symptom scores by subject report (itching eyes, itching nose, itching throat, itching mouth/palate), and nasal peak inspiratory flow (PIFn) and peak expiratory flow (PEFn).

Results: Significant reductions in severity of symptom scores were found for sneezing, running nose, running eyes and itchy mouth/palate ($p \leq 0.05$). No significant differences were found in the results for itchy eyes, itchy nose, itchy throat, ECPs, PIFn and PEFn. No adverse events occurred.

Conclusions: The results show that the device significantly reduced some hay fever symptoms. The study would have been improved if compliance was monitored electronically and if nasal congestion was monitored by report. The mode of action is unclear. The study does not consider long-term implications of the therapy.

Introduction

The prevalence rate of hay fever (seasonal rhinitis) has increased notably in Western Europe in the last few decades. It imposes a severe socio-economic cost and decreases the quality of life in a large section of the population. For example, in the UK, which has one of the highest prevalence rates in the world, the prevalence rate for the population as a whole is c. 25% and the rate in teenagers is approximately 38%. The percentage rate of increase in prevalence has slowed to less than 1% p.a. in the UK in recent years but it has not halted[1].

Many treatments and remedies are available for hay fever either on prescription or on sale over the counter from pharmacies. However, many of these can have side-effects or they may not be suitable for some people, such as pregnant women. Previous published work has indicated that exposure to the inside of the nose with certain wavelengths of light can reduce the symptoms of allergic rhinitis. This work has been done mostly in Eastern Europe and has been on perennial rhinitis. For example, Koreck *et al.*[2] investigated whether phototherapy with a combination of ultraviolet light (UV-B, UV-A) and visible light was effective in treating allergic rhinitis. They concluded that phototherapy was an effective modality in treating allergic rhinitis and that it offered new options for treatment of immune-mediated mucosal diseases. Similar positive results were reported by Csoma *et al.*[3] from an open study in Hungary. Hu and Li [4] examined the effects of far infrared treatment and concluded that it could improve symptoms of allergic rhinitis. Kemeny and Korec[5] conducted two open studies in Hungary using low dose UV-B, UV-A and visible light to investigate the mechanism of action. They reported that the light treatment reduces the antigen presenting capacity of cells, and inhibits synthesis and release of pro-inflammatory mediators from several cell types. The effect of narrow-band red light phototherapy was investigated in a study by Neuman and Finkelstein[6] in Israel. They concluded that in uncomplicated cases of allergic rhinitis (no polyps or other relevant problems), red light illumination led to marked alleviation of symptoms.

No double-blind placebo-controlled trials had been done to explore the effect of phototherapy on hay fever. The trial reported in this paper was conducted with the objective of investigating the effect of the phototherapy device SN-206* on symptoms of hay fever (seasonal rhinitis) due to grass pollen in adults. This class IIA medical device has two probes which are inserted high into the nostrils and which emit infrared light (652 nm and 940 nm) delivering 0.54 joules/cm^2 per 3-minute cycle.

It had been on sale over the counter for the 15 months prior to the trial. During this time approximately 50 000 units were sold. No adverse effects were reported but the efficacy had not been assessed.

Patients and methods

Basic study design

The trial is a randomised placebo-controlled double-blind, grass pollen challenge conducted out of the pollen season (late October 2008 to January 2009), on 101 adult male and female hay fever sufferers (sample size determined by power calculation). Exclusion and inclusion criteria applied. The placebo devices looked like the active units but emitted low intensity visible light which had a red tinge due to coloured plastic covers. Instead of delivering the light high into the nostrils the light was emitted at the base of the probe beneath the nostrils. The placebo and real units were in identical boxes but were labelled A and B. The boxes were given to the subjects unopened to maintain double blinding.

Ethical considerations

NHS ethical approval was given at the Royal National Orthopaedic Hospital (Joint RNOH/ICMS REC) Stanmore in September, 2008. The study complies with the Declaration of Helsinki.

Patients

A total of 112 adult patients, male and female, mean age 26.9, range 18–65 years, SD 12.6, were recruited from the Worcester area. Of these, 101 completed the trial (Table 1). The sample size was set by a power calculation based on a multiple endpoint. The information for this was obtained from previously published research on rhinitis which indicated the probable response effect of the device on the main symptoms (outcome variables) and the standard deviation of these. From these it is assumed that the standard deviation of the response variables is 1.5 units and that the true difference between treatments is 1.609 units. With a significance level (alpha) set at 0.05 for a two-sided test the power calculation indicated that a sample size of 50 in each group was required to give a power of 1.00. This is higher than the default level of 0.80 and allowed for some drop-out of participants.

Potential volunteers were sent a baseline questionnaire before the trial which included questions on age, name and address of GP; whether they had symptoms of hay fever in both of the last two summers, which months they had symptoms in, severity of seven types of symptoms as none, slight, moderate or severe (namely frequent sneezing, itchy eyes, blocked nose, running nose, running eyes, headache/tiredness, itchy throat/mouth); whether they took medication for hay fever, if yes, whether this was with prescription or not, details of the treatments used; whether they had asthma, if yes, then whether they took steroids for it and whether it got worse in the summer months; whether they had sinusitis, nasal deformity or polyps; whether they had been given a skin test in the last

*The phototherapy device SN-206 is manufactured and distributed by Lloyds Pharmacy Ltd, UK

Table 1. *Participant profile of the 101 subjects who completed the trial. Information from baseline questionnaires. All of these people met the exclusion and inclusion criteria specified in the protocol*

	Placebo	%	Active	%
A. Demographics and symptom profiles				
Number in group	51		50	
Age				
18–27	31	60.8	26	52.0
28–37	7	13.7	10	20.0
38–47	7	13.7	9	18.0
48–57	5	9.8	3	6.0
58+	1	1.9	2	4.0
Gender				
Male	30	58.8	29	58.0
Female	21	41.2	21	42.0
Total symptoms (totals for 7 symptom types)				
None	44	12.3	36	10.2
Slight	80	22.4	89	25.4
Moderate	158	44.25	148	42.3
Severe	70	19.6	65	18.6
Number of people reporting two or more symptoms as 'none'	13	25.5	11	22.0
Number of people reporting two or more symptoms as slight	23	45.1	27	54.0
Number of people reporting two or more symptoms as moderate	45	88.2	45	90.0
Number of people reporting two or more symptoms as severe	21	41.1	18	36.0
B. Indicators of allergy profiles				
Skin allergy test				
House dust mite (Der p1)	19	37	17	34
Mixed tree	22	43	18	36
Weed	13	25	11	22
Cat	14	27	19	38
Medication source for hay fever				
Prescriptions from GP	16	31	16	32
OTC*	35	69	34	68
Medication types used for hay fever				
Eye drops	18	35	16	32
Nasal spray	27	53	22	44
Antihistamines	36	71	39	78
Herbal/homeopathic	5	1	3	0.6
Steroids	2	0.4	0	0
Other	1	0.2	1	0.2

There were no significant differences in the profiles of the two groups ($p \leq 0.5$)
*OTC, over the counter

12 months for grass pollen and if so what the result was. Suitable subjects were invited for a skin allergy test, if they had not had one in the previous year. Informed consent was obtained. Selection was then based on the following inclusion and exclusion criteria. Inclusion criteria were: a history of hay fever in the grass pollen season during both of the last 2 years with symptoms that have needed treatment or remedies from pharmacies or on prescription; positive skin prick test result for grass performed within the last 2 years; male and female adults 18 years old and over. Principal exclusion criteria were; history of asthma; people with nasal deformities leading to obstruction; people with perennial rhinitis or nasal polyposis; pregnant or lactating women; any other adverse medical conditions such as sinusitis, cardiac, renal or hepatic disease. In addition, just before the pollen challenge the subjects were interviewed and the following additional exclusions were applied: subjects with upper respiratory viral infections; subjects who used oral antihistamines in the

previous week or corticosteroids in the last 30 days; subjects who appeared to have or reported any symptoms of illness; subjects who had not used the device for the correct time; subjects who had symptoms of cold or rhinitis lasting more than 2 days or flu during the therapy time or on the day of the trial. Subjects with occasional extra-seasonal rhinitis were not excluded from joining the trial although they were excluded if they were experiencing such symptoms during the use of the device or at the time of the pollen challenge.

Study design

All subjects used the devices (active or placebo) for 3 min three times a day 5–6 h apart for 14 days prior to pollen challenge. This usage was based on the recommendations provided by the manufacturer. They were instructed to report any adverse effects by telephone immediately to the study centre. A 24-hour mobile number was available for this.

Before the start of each challenge trial the subjects were interviewed to explain the procedures in detail and to check for exclusion criteria. Informed consent was confirmed. Usage of the device was checked from diary cards and interview with the subjects. Baseline symptom scores were recorded and a sample of nasal secretions was taken for analysis for eosinophil cationic proteins (ECPs). This was done by inserting a pre-weighed strip of Whatman number 1 filter paper (Whatman Ltd, UK) into the nostril (left and right separately) following the methodology of Knowles *et al.*[7] which is acceptable to subjects and minimises stimulation that could lead to extra sneezing or secretions. The strips were stored in Eppendorf tubes (pre-weighed and labelled), re-weighed then frozen until analysis. Any with blood contamination were discarded. Baseline nasal peak inspiratory flow (PIFn) and nasal peak expiratory flow (PEFn) were taken (best of three noted) using a computerised analysis system (Vitalograph 2120 operated with the Vitalograph Spirotac 4.20 software).

An allergen challenge of grass pollen (*Dactylis glomerata*, Allergon AB, Sweden) was delivered to the nostrils by a Morrow-Brown micro spoon[8] equivalent to the allergen load on a high pollen count day (350 grains pollen per cubic meter air). This technique has been used previously by the authors[9]. The challenge was delivered in a challenge laboratory with personnel wearing protective clothing and masks. *Dactylis glomerata* is widespread in the UK and is one of the 10–12 grasses that contribute most to the grass pollen load of the air. There is a high degree of cross-reactivity between the majority of grass pollen from the approximately 150 different species in the UK[10].

At baseline and at regular intervals after challenge scores were taken for sneezing, itchy eyes, running eyes, running nose, itchy nose, itchy throat and itchy throat/palate graded as symptoms 0 = absent, 1 = very mild, symptoms hardly noticeable, 2 = mild, symptoms noticeable intermittently 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 daily activities constantly. Symptom scores were taken at baseline (before challenge) then after challenge at 30 s, 6, 15, 30, 45, 60, 90, 120 and 150 min.

Nasal secretions were sampled at baseline then following challenge at 1, 15, 35, 60 and 120 min. Measures were taken of PIFn and PEFn at baseline, then following challenge at 3, 15, 45, 90 and 150 min. The samples of nasal secretions taken at baseline before challenge and through the trial were analysed for ECPs using the Pharmacia Unicap system by the Department of Immunology, Northern General Hospital, Sheffield, UK.

The primary outcome measures were observed severity scores for symptoms (sneezing, running nose and running eyes) and the amount of ECPs present in nasal secretions. The secondary outcome measures were symptom scores by subject report (itching of nose, itching of throat, itching of mouth/palate, itching of eyes), PIFn and PEFn. The subjects were assessed by a medical officer before leaving. The subjects and researchers did not know the identity of the real or placebo devices until after the analysis was completed. Nasal obstruction was not scored since an objective measure of nasal inspiratory and expiratory flow rate was used.

Subjects

The recruits were selected on the basis of replies to a baseline questionnaire, an interview covering the baseline questions and the results of a skin allergy test. The subjects were assigned to either group A (placebo) or B (active) by stratified random sample based on age range, gender and severity of reported symptoms. The allocations were made based on throw of a dice (even numbers A (placebo), odd numbers B (active). The identities of the two groups were blinded until after the trial.

Statistical analysis

In most cases non-parametric statistics were applied as these do not assume normality and can be used to test ordinal variables. For example the Mann–Whitney

U/Wilcoxon and Smirnov tests were applied to investigate significant differences. Parametric tests, including the Student *t*-test, were used where possible in the cases of interval scale data. The level of probability was set at 0.05 or higher for acceptance. Standard deviations (SD) and confidence intervals (CI) are given for comparisons but in some cases the data sets are highly skewed.

Results

The profiles of the 101 adult subjects (male and female) who completed the trial are given on Table 1. There were no significant differences in the features reported in the baseline questionnaire between the two groups of subjects who completed the trial ($p \leq 0.5$). The challenge was given outside of the pollen season and the subjects were screened for relevant symptoms before challenge and excluded if they had them, so they were free of symptoms before challenge.

Of the 11 who did not complete the trial, eight did not keep the appointment for the challenge test or could not attend on a suitable date, one stopped using the device, one had symptoms of severe viral infection and one had a previously undisclosed history of sinusitis.

All the subjects had some reactions to the pollen challenge, but not all subjects experienced all symptoms. The overall mean score per participant for all symptoms was 49.3 for the placebo group and 35.5 for the active group (Table 2). These were significantly different at $p \leq 0.01$. No adverse reactions occurred.

Average symptom scores for each category

In all cases the average symptom scores for the placebo group were higher than those in the active group (Figure 1, Table 2). The highest symptom scores were for itching nose, running nose and itching throat. The lowest scores were for the eye symptoms.

There was an overall difference of 28% in total symptom scores between the two groups and an overall difference of 27% for mean scores per subject (Table 2). The percentage differences varied between symptom types, ranging from 46% difference for total scores for running eyes (44% for means) to 18% difference for total scores for itching throat (17% for means).

Primary outcome measures

Sneezing

The mean sneezing scores for the different measurement times after challenge were significantly different

Table 2. *Summary data for symptom scores*

Symptom	Placebo					Active					% Difference	
	Total score	Mean per person	Range	SD	CI	Total score	Mean per person	Range	SD	CI	Total scores active/placebo	Total mean active/placebo
Sneezing	280	5.5	0–18	4.4	1.2	182	3.6	0–15	3.6	0.9	35	35
Itching eyes	152	3.0	0–13	3.5	1.0	117	2.3	0–20	4.2	1.2	23	23
Running eyes	163	3.2	0–11	3.2	0.9	88	1.8	0–17	3.4	0.9	46	44
Itching nose	527	10.3	0–22	2.6	0.7	407	8.1	0–38	7.4	2.1	23	21
Running nose	697	13.7	0–29	2.3	0.6	494	9.9	0–35	7.1	1.9	29	28
Itching throat	396	7.8	0–28	8.7	2.4	323	6.5	0–30	7.4	2.1	18	17
Itching mouth	297	5.8	0–25	8.0	2.2	164	3.3	0–30	6.0	1.7	45	43
Overall total	2512	49.3	13–127	26.2	7.2	1775	35.5	3–142	24.8	6.9		

SD, standard deviation; CI, confidence interval

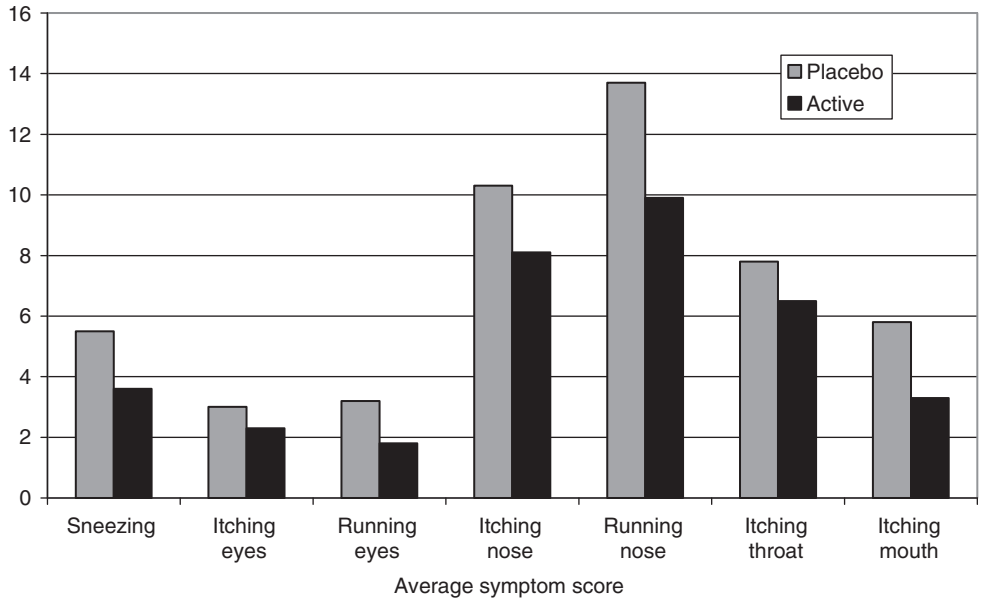

Figure 1. *Average symptom scores per subject for all symptom categories. Differences were significant (p ≤ 0.5) for sneezing, running eyes, running nose and itching mouth. Differences were not significant for itching eyes, itching nose and itching mouth*

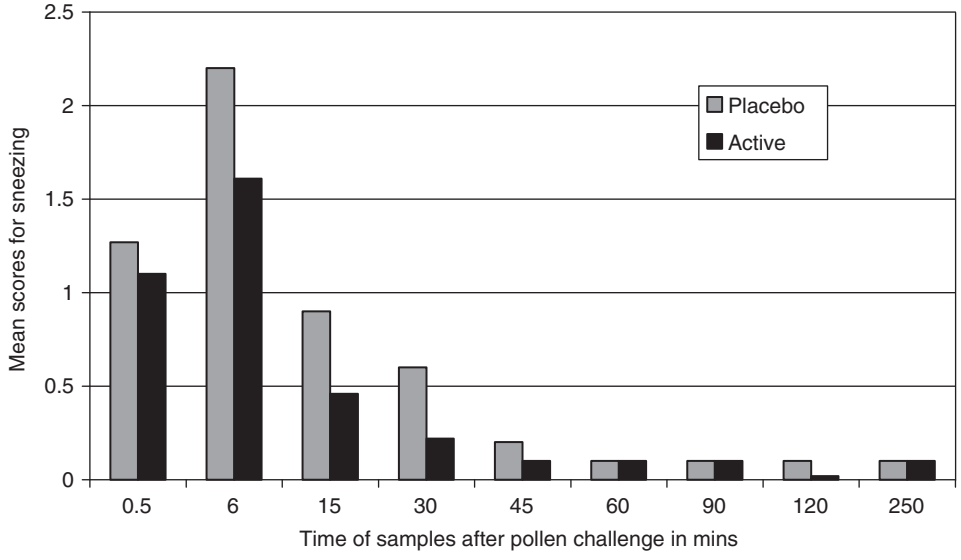

Figure 2. *Mean symptom scores for sneezing at times after pollen challenge. These were significantly different (p ≤ 0.5), with the maximum difference occurring in the samples taken at 6 min after challenge*

at the $p \leq 0.05$ level between the placebo group and the active group (Figure 2). For the placebo group the overall mean was 0.62 with SD = 0.73 and CI = 0.48. For the allergy reliever group the overall mean was 0.42 with SD = 0.55 and CI = 0.27.

There was a significant difference ($p \leq 0.05$) between individual participant's total scores for sneezing in the placebo group versus those in the group with active devices. For the placebo group the total was 280, mean 5.45, with SD = 4.4 and CI = 1.2. For the active group the total was 182, mean 3.64, with SD = 3.6 and CI = 0.9.

Running nose

The mean scores per individual for running nose for the different measurement times after challenge were significantly different ($p \leq 0.05$) (Figure 3). For the placebo group the overall mean per subject = 1.46 with SD = 3.82 and CI = 2.50. For the active group the overall mean per subject =1.07 with SD = 2.81 and CI = 1.84.

Total scores for running nose for each participant in the placebo group were significantly different at $p \leq 0.05$ from those in the active group

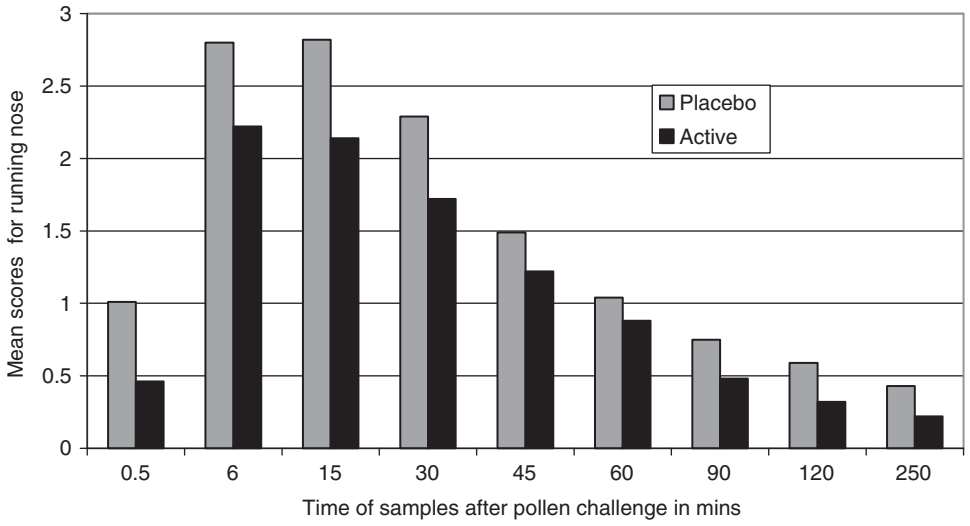

Figure 3. *Mean symptom scores for running nose at times after pollen challenge. These were significantly different (p ≤ 0.5), with the maximum difference occurring in the samples taken at 15 min after challenge*

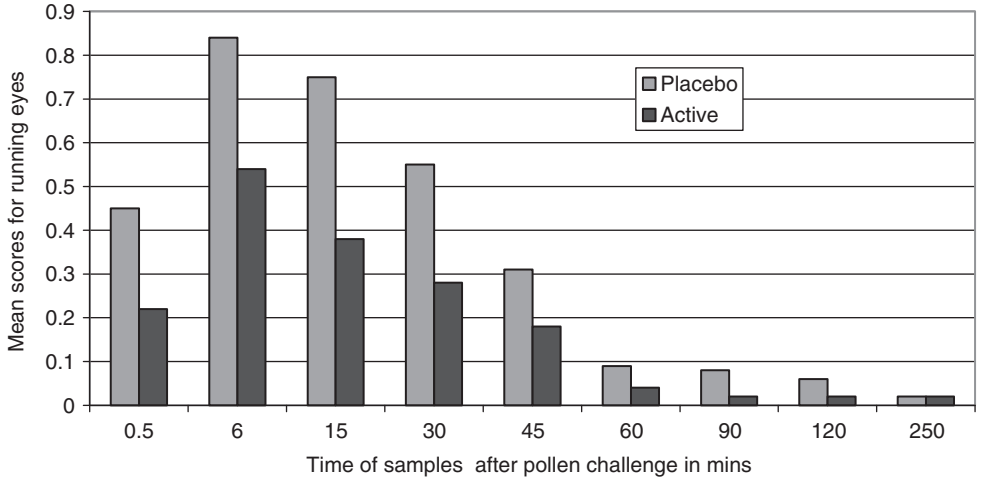

Figure 4. *Mean symptom scores for running eyes at times after pollen challenge. These were significantly different (p ≤ 0.5), with the maximum difference occurring in the samples taken at 15 min after challenge*

(Smirnov test). Total symptom scores for running nose in the placebo group = 697, mean 13.7, SD = 2.3 and CI = 0.6. The total scores for running nose in the active group = 494, mean = 9.9, SD =7.1, CI = 1.9.

Running eyes

The mean symptom scores for running eyes (Figure 4) for the different measurement times after challenge were significantly different for the placebo group versus those for the active group ($p \geq 0.05$). For the placebo group the overall mean = 0.35, with SD = 0.93 and CI = 0.61. For the active group the overall mean = 0.19 with SD = 0.51 and CI = 0.33.

The total symptom scores for individuals for running eyes in the placebo group were significantly different from those in the active group ($p \leq 0.05$). The mean of the placebo group was 3.16, with SD = 3.2 and CI = 0.9. For the active group the mean = 1.8 with SD = 3.4 and CI = 0.9.

Eosinophil cationic proteins (ECPs)

Some of the filter samples for the nasal secretions were unsuitable for analysis for ECPs, (e.g. traces of blood contamination) so samples from only 49 subjects were analysed from the placebo group and 49 subjects from the active group. The results show a wide variance in both groups. There were no significant differences in the results for the ECP concentrations between the two groups at baseline. In some cases the concentration of ECPs in the samples decreased from the baseline

amounts to the first sample after challenge. Parametric and non-parametric tests including analysis of variance, tests of significant differences between means and tests of differences in dispersion were applied. No significant differences were found either when comparing the pattern of results for the various times after challenge or when comparing the individual results between the two groups at specific sample times.

Secondary outcome measures

Itchy eyes, itchy nose and itchy throat

No significant differences were found between the mean symptom scores for itchy eyes, itchy throat and itchy nose for the two groups at different times after challenge or for the results for individuals overall.

Itchy mouth/palate

The mean scores per subject for itchy mouth/palate at the measurement times after challenge (Figure 5) were significantly different ($p \leq 0.05$). For the placebo group the overall mean = 0.64, with SD = 0.57 and CI = 0.42. For the active group the overall mean = 0.36, with SD = 0.27 and CI = 0.24.

The total scores for itchy mouth/palate for individual participants for the placebo group are significantly different from those for the active group ($p \leq 0.05$). In the placebo group mean = 5.82, SD = 8.0, CI = 2.2. For the active group mean = 3.26, SD = 6.0, CI = 1.7.

Nasal flow readings

No significant differences were found in the results for PIFn when comparing the data for the measurements at the times after challenge. Similarly no significant differences were found in the data for the two groups when considering the results for individual subjects. Tests were applied for overall results per subject and for those for individual sample times.

No significant differences were found in the results for PEFn when comparing the data for the measurements at individual times after challenge. Similarly no significant differences were found in the data for the two groups when considering the results for individual subjects.

Discussion

The amount of pollen challenge given to the subjects was equivalent to the grass pollen concentration on a very high pollen count day. It was delivered to the nose in one dose and so presented a robust challenge. All of the subjects experienced some symptoms. These differed in severity within both groups reflecting the range of sensitivity to pollen reported in the baseline questionnaires. The subjects were assigned to the placebo or active phototherapy groups at random but were matched by gender, age ranges and reported symptom severity before the trial. The objective signs of sneezing, running eyes and running nose were assessed by trained and experienced National Pollen and Aerobiology Research Unit staff in order to minimise variance. The subjective symptoms which were monitored by subject report and assigned symptom scores (itching of eyes, itching of nose, itching of throat, itching mouth/palate) could be prone to inter subject variance due to the opinions of the individual participants about how bad their symptoms were. There were few differences between the groups in the results for itchy eyes, itchy throat and itchy nose (all not significantly different between placebo and active groups).

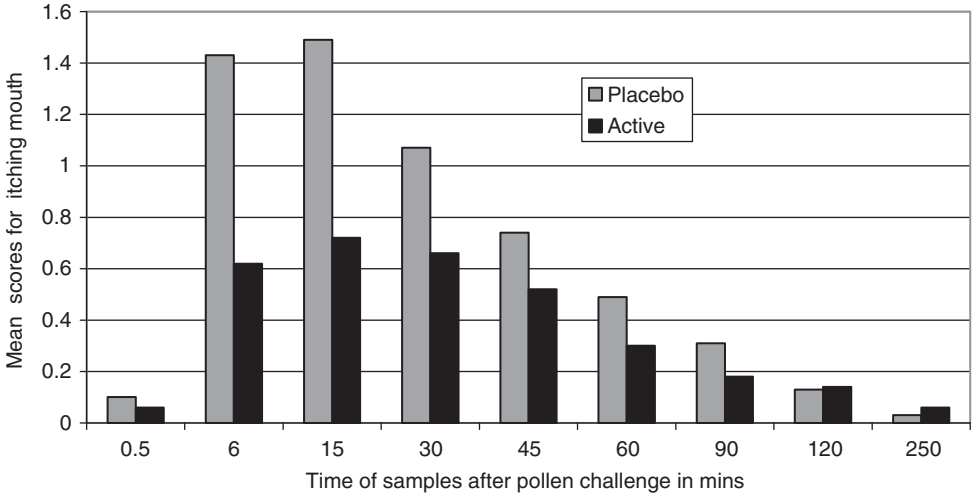

Figure 5. *Mean symptom scores for itchy mouth/palate at times after pollen challenge. These were significantly different ($p \leq 0.5$), with the maximum difference occurring in the samples taken at 6 min after challenge*

Some of the subjects in both groups had blocked noses at some stage during the trial after pollen challenge and for some samples they could not breathe sufficiently freely through the nose to give a reading into the nasal spirometer. The PIFn and PEFn results may have been influenced by this but it is not possible to determine to what extent this problem may have distorted the results. Nearly all of the subjects had some decrease in PIFn and PEFn after challenge but the differences between the two groups were not marked. The addition of monitoring nasal congestion would have added to the information on rhinitis symptoms and would have given a more comprehensive analysis.

In the case of the ECPs the results showed wide variations within groups. This could be due to several factors including the fact that eosinophilic inflammation has a minor role in allergic subjects out of season in the 120 min after a challenge. The weight of secretions collected on the filters were significantly higher at $p \leq 0.05$ level in the placebo group than in the active group both in the cases of the sample at 30 min after challenge and at 60 min after challenge. This difference was already detected in the symptom of running noses between the groups and does not provide information about the ECPs. All of the subjects were screened for symptoms in the period immediately prior to challenge and were asked if they had experienced any symptoms, particularly of allergy or cold, in the previous 24 h. Any subjects with symptoms were excluded. It is not clear why a few of the ECP readings reduced slightly immediately after challenge but it may have been because of dilution due to increased secretion. It is also possible that some subjects may have been reacting to an allergen prior to challenge. The time interval between the baseline sample and the first post-challenge sample was about 10 min. There was no significant difference in the numbers of subjects with ECP reduction after challenge between the active and placebo groups.

A physical examination of the nose after use of the device was not made because we did not have any reason to believe that 3 minutes of use 4 times a day for 14 days could possibly produce any alteration of the mucosa sufficient to be detected by direct nasendoscopy and we really did not feel that nasal mucosal biopsy was justified in this trial.

Compliance in the use of the device for the trial was monitored by diary cards and by interview with the subjects before challenge. This relied mostly on the honesty of the subjects. People with cards that looked as if they had been filled in for all or several days at one time were questioned closely about this and were not entered into the trial if it was suspected that the device had not been used as instructed. It would have been useful to monitor compliance electronically on the devices as non-compliance could have been a source of variance and error across all observations and measurements.

It has been suggested that the device could possibly have unknown side-effects and could cause intranasal tumours such as melanomas, and for this reason, long-term, adequate safety data should be collected. However, near infrared light is used in a multitude of medical diagnostic tests and even used for spectroscopy following transmission through fetal skull and brain. It is also used in optical rhinomanometry in both adults and children with no side-effects having been recorded. Clearly there has been insufficient clinical use of the device to establish long-term safety data at this point. Long-term safety was not considered in this study. Generally there is a lack of previous work on the use of near infrared light in the treatment of allergy and very few papers have been published on this topic.

We are confident that we can rule out a placebo effect of the device due to the visual impact of the placebo. However, the mechanism of action is not fully understood. Apart from the light, some heat is generated. It may be that the mucosal effect of this heat could alter mucosal blood supply and inflammatory effects. It is clear that the near red light therapy was able to reduce symptoms during an allergen challenge which are mainly sustained by massive release of histamine. This indicated that the therapy has modified this histamine release. There are various reasons as to why this may have taken place. Red light is known to suppress reactive oxygen species possibly as a result of activation of superoxide dismutase or activation of catalase[6,11,12]. Changes have also been reported in calcium transport in response to red light[13] and calcium mobility is important in the allergic reaction[14]. Further research is required on the effect of the device on the allergic response, particularly on the reactions in the nasal mucosa.

The results from the trial show an overall difference of 29% between the total symptom scores for the placebo and the phototherapy groups (28% for the mean). For individual symptom types the differences in the results for the means per subject range between 44% for running eyes to 17% for itching throat. These results need to be viewed in the context of the efficacy of other treatments. None of the medications or treatments for hay fever which are available for sale over the counter or with prescription (except immunotherapy, e.g. sublingual immunotherapy) will control the symptoms of hay fever completely when the pollen count is high. For example, break-through symptoms can occur with antihistamine use during the peak of the pollen seasons. A treatment which can significantly reduce some symptoms of hay fever and which has no known

side-effects, could offer a useful alternative or supplement to pharmacological treatments.

We did not undertake a low or moderate pollen challenge in these subjects and so it is not possible to determine how effective the allergy relieving device could be for lesser concentrations of pollen. Hay fever sufferers usually have their most severe symptoms when the pollen count is high so investigating the alleviation of symptoms in these conditions is most important.

Conclusion

The results of this double-blind placebo-controlled trial show that the SN-206 phototherapy device significantly reduced some of the main manifestations of hay fever, that is sneezing, running nose and running eyes. It also significantly reduced the symptoms of itchy mouth/palate. The results did not show any significant reduction in the symptoms of itchy eyes, itchy nose and itchy throat or in the amount of ECPs present in nasal secretions. The results did not show any significant differences in nasal peak expiratory flow or in nasal peak inspiratory flow between the active and placebo groups. The monitoring of symptoms would have been improved by inclusion of a subjective measure of nasal blockage. Further research needs to be conducted on the mode of action of the device and the safety issues of long-term use.

Transparency

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This trial and the publication of this article were sponsored by Lloyds Pharmacy. Lloyds pharmacy did not have any role in designing or conducting the trial of the device. They had no role in drafting, writing or reviewing this article and have not seen the manuscript at any stage. The authors take full responsibility for the views expressed in this article which may not be shared by the sponsors.

Declaration of financial/other relationships
J.E. and R.L. have disclosed that they have no relevant financial relationships.

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