

# 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

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## Introduction

Inert cellulose powder has been on sale in the UK as a remedy for hay fever since 1994. It is applied to the inside of the nose where it forms a gelatinous coating. The results of a double blind placebo controlled study which the authors conducted on 98 hay fever sufferers over the 2004 grass pollen season showed that the active product group used significantly less rescue medication than that using the placebo (Current Medical Research and Opinion 2006;22:2:275-285). The aim of this study was to explore the effects of the cellulose powder in controlling symptoms when subjects are not taking any medication.

## Method

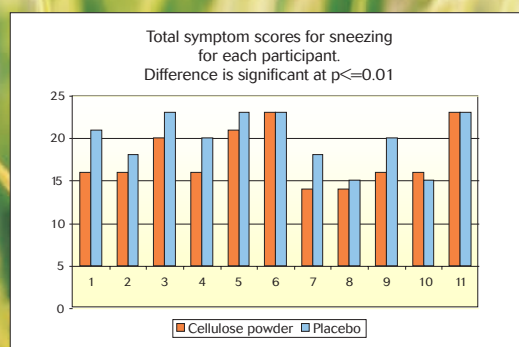
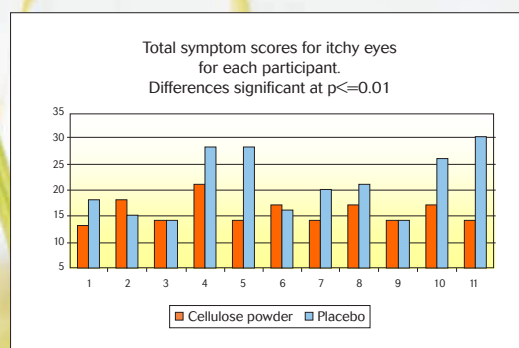
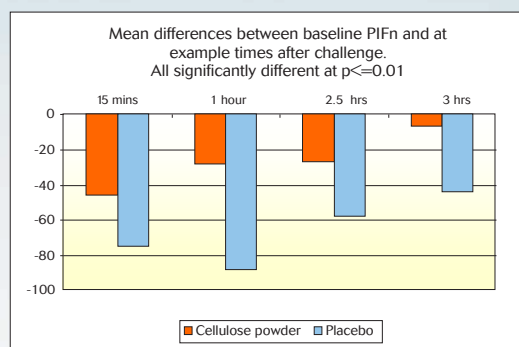
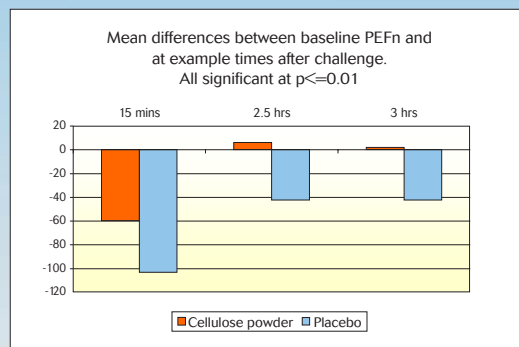
A double blind placebo controlled cross over trial was conducted on 11 adult hay fever sufferers (diagnosed to be allergic to grass pollen but not to tree pollen by SPT and who had symptoms in the previous two summers). The sample size was set by a power calculation. The trials were in the spring before the grass pollen season. The placebo was lactose powder. Exclusion criteria were applied e.g. those with perennial rhinitis or asthma. Ethical approval was given by the National system of research ethics committees. Powder (real or placebo, order randomised) was put into the nose, followed by grass pollen equivalent to 350 grains per cubic metre air. At baseline and at regular intervals after challenge, scores were taken for 6 symptom categories, nasal secretions were sampled for ECP, and measures were taken of nasal peak inspiratory and expiratory flow. All measurements were continued in the clinic for 4.5 hours, then symptom scores and basic lung function were repeated at 6.5 hours and at 24 hours after challenge.

## Results

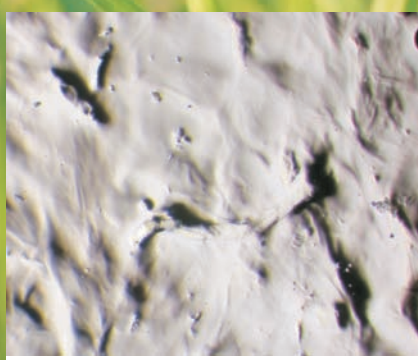
Significant differences ( $p \leq 0.05$  and  $p \leq 0.01$ ) occurred in the data at various times from challenge in peak nasal expiratory flow between placebo and active treatments, and also in nasal PIF, in sneezing and in itching eyes. The results for other lung function tests and symptoms were slightly under the level for significance. The results for the nasal secretions were significantly different at  $p \leq 0.05$ . No adverse reactions occurred.

## Conclusion

The results of the trial show that the inert cellulose powder can have significant effects in reducing symptoms of sneezing and itchy eyes due to grass pollen allergy. It can also have significant effects in reducing nasal inflammation, as measured as nasal PEF, PIF and as ECP in secretions. The results indicate that the use of inert cellulose powder can help to alleviate symptoms of hay fever.



Nasaleze powder dry (taken from 100 x magnification)



Nasaleze powder after exposure to damp surface (taken from 100 x magnification)

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