

## Hayfever vaccine study raises hopes for new allergy treatment as clinical trial is launched

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Researchers are developing a new vaccine for hayfever which could be more effective, less invasive for patients and less expensive than vaccines already available to patients within the NHS.

Scientists at Imperial College London and King's College London have carried out a study which showed a significant reduction in skin sensitivity to grass pollen that was associated with an increase in 'blocking antibodies' in the <u>bloodstream</u>. The results are so encouraging that King's has today launched a clinical trial in collaboration with Guy's Hospital, working together as part of King's Health Partners. The trial is funded by the Medical Research Council and National Institute for Health Research via the Efficacy and Mechanism Evaluation programme, and will further investigate the vaccine as a potential new hayfever treatment.

The researchers say the approach defines a completely new concept in treating allergies and in the future could have an impact on treating other conditions such as asthma and food allergies.

Hayfever affects one in four people in the UK. An allergic reaction to grass pollen triggers a blocked or <u>runny nose</u>, sneezing, itchy eyes and in some cases <u>asthma symptoms</u>. For many individuals this can interfere with work or <u>school performance</u>, sleep and social activities. Tablets and sprays may temporarily relieve symptoms, but for severe cases one option is a vaccine to 'switch off' the allergy, called immunotherapy.



The vaccines currently used involve high doses of allergen given by injection underneath the skin (subcutaneously) or sometimes as a daily tablet or drops under the tongue. In most cases this involves large numbers of injections in an NHS allergy clinic or daily tablets/drops taken continuously, which can be inconvenient for patients and expensive for the NHS.

Published today in the <u>Journal of Allergy and Clinical Immunology</u>, this new study shows that a series of low dose <u>allergen</u> injections (less than a 1000th of the usual dose) into a higher layer of the skin (intradermally), rather than subcutaneously, led to a 90 per cent reduction in skin reactivity to grass pollen.

Researchers administered the vaccine intradermally to volunteer hayfever sufferers from Royal Brompton and Harefield NHS Foundation Trust. One group of subjects received six injections of grass pollen extract at two-week intervals over 10 weeks. The participants' allergic responses in the skin were then measured. The initial injection provoked an allergic reaction on the arm visible as a lump around 10 cm in diameter lasting 1-2 days. Over time a dramatic 90 per cent reduction was seen in the size of the lump suggesting that the allergic reaction was gradually being switched off with each injection. The size of the lump did not decrease in another group of subjects who received only two injections separated by 10 weeks.

During the study none of the participants reported unwanted side-effects and the injections did not trigger hayfever symptoms.

The researchers believe that the method of injecting the vaccine intradermally is a major factor in its success, as the skin is a highly active immunological area – more so than underneath the skin where allergy vaccines are traditionally administered.



Dr Stephen Till, Senior Lecturer at King's College London, said: 'The results of our study are hugely exciting. We now want to find out if this process can also switch off grass allergy in the nose and improve hayfever symptoms, so we are today launching the PollenLITE clinical trial to further test our new approach.'

Professor Stephen Durham, Head of Allergy and Clinical Immunology at Imperial College London, said: 'There is great interest in giving immunotherapy by novel alternative routes to improve uptake by the immune system. The results of this study provide an excellent foundation for going on to test the intradermal vaccine route in clinical trials.'

King's College London and Guy's and St Thomas' NHS Foundation Trust, as part of King's Health Partners Academic Health Sciences Centre, are today launching the PollenLITE trial to test this new vaccine. The trial is a collaboration with Imperial College London, which together with King's College London forms the basis of the MRC and Asthma UK Centre in Allergic Mechanisms of Asthma.

The PollenLITE team is looking for 90 hayfever sufferers to take part. Volunteers will receive either seven injections of small quantities of grass pollen into the dermis, or a placebo (dummy) injection in early 2013. In the summer of 2013 study participants will record their symptoms daily and scores will later be compared in the two groups. Small samples of skin and blood at the beginning and end of the study will be taken for experiments into how this new treatment works.

Dr Till at King's concluded: 'Hayfever is one of the most common diseases in the UK and can have a serious impact on people's everyday lives. PollenLITE is a major trial that has the potential to identify a new treatment that is more effective, convenient and cheaper for the NHS than the current alternative.



'Crucially, if this approach proves to be effective it would define a new scientific and clinical principle that could also be applied to other allergic diseases such as asthma and food allergies. This could be a pivotal study in immunological research.'

## Provided by King's College London

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