

A step forward in the treatment of chronic urticaria

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An international study involving dermatologists from the Hospital del Mar and Spanish subjects has concluded that a drug normally used to treat severe bronchial asthma caused by allergies (Omalizumab) rapidly eliminates the symptoms of spontaneous chronic urticaria, a development that it is expected will significantly improve the quality of life of chronic urticaria sufferers.

Spontaneous chronic urticaria, one of the most common skin diseases, consists of an abrupt reaction that results in hives or stains of different shapes and sizes on the surface of the skin that grow and produce a very intense itch. Sufferers can develop dozens of hives each day for months or years. When the condition persists for more than 6 weeks, it is referred to as chronic urticaria and can last between approximately 5 and 10 years, adversely affecting the quality of life of the sufferer in both physical and emotional terms.

Approximately 50% of urticaria patients do not respond to treatment with standard doses of non-sedative antihistamines, and require a heavier dose of antihistamines. Some people even require immunosuppressors, such as corticoids and [cyclosporine A](#), to control the condition. These immunosuppressors have significant side effects.

The study, in which Dr. Ana Giménez Arnau, a dermatologist at the Hospital del Mar and researcher with the group conducting research on inflammatory dermatological diseases at the IMIM (Hospital del Mar Medical Research Institute) was involved alongside institutions from Germany, the United States, and the United Kingdom, demonstrated that Omalizumab, a biological treatment that prevents immunoglobulin E from joining up with the receptor of the cells that triggers the urticaria, the mast cell, radically eliminates clinical symptoms (itching) and signs of urticaria (hives) in patients for whom [antihistamines](#) are ineffective.

The research, which has consisted of an international Phase III clinical trial conducted across several centres of research, has run for 7 months and involved 323 patients from different countries. These patients have an average age of 42 and for the most part are women (76%), a description that accurately reflects the profile of patients with chronic urticaria.

At 4-week intervals over a period of three months, participants were randomly given doses of 75, 150, and 300mg of Omalizumab or a placebo drug using the double-blind method and their condition monitored. "In week 12, we can see a significant difference between the groups that receive doses of 150mg or 300mg of Omalizumab and those who receive a dose of 75mg or the placebo drug. The itching and the urticaria totally disappeared in 23% of patients administered a dose of 150mg, and in 53% of patients administered 300mg of [Omalizumab](#)", explains Dr. Giménez Arnau. She also adds that "the therapeutic objective is the full remission of symptoms in order to continue the therapy over a number of months before gradually phasing it out, resulting in the complete elimination of the disease".

This drug, for which US and European authorities will begin the registration process for treating this condition, is superior to the immunosuppressors currently used to treat serious cases in its very fast effectiveness in 90% of patients and ease of use (once a month), as well as the fact that it has many fewer side effects. If registered, it could be available for use in treating chronic urticaria in 2014.

This is the first of three international clinical trials and, while the results thus far are very promising, further research is required to determine the exact role of this drug, its possible side effects, and the doses to be administered. This research gives hope to many people who have been waiting years for a solution, people who suffer with chronic urticaria on

a daily basis and whose quality of life is greatly affected by the condition (itching, sleeplessness, psychiatric problems such as anxiety or depression), and a hope of eliminating the socioeconomic impact of the disease for society, since sufferers of chronic urticaria require constant medication to control the symptoms of their condition.

More information: Omalizumab for the Treatment of Chronic Idiopathic or Spontaneous Urticaria.

Maurer M., Rosen K., Hsieh H.J., Saini S., Grattan C., Giménez-Arnau A.M., Agarwal S., Doyle R., Canvin J., Kaplan A., and Casale T. *New Engl J. Med.* 2013. DOI: [10.1056/NEJMoa1215372](https://doi.org/10.1056/NEJMoa1215372)

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