Article:
Denman, S, Ford, K, Toolan, J et al. (4 more authors) (2016) Home Self-Administration of Omalizumab for Chronic Spontaneous Urticaria. British Journal of Dermatology, 175 (6). pp. 1405-1407. ISSN 0007-0963

https://doi.org/10.1111/bjd.15074

Home Self-Administration of Omalizumab for Chronic Spontaneous Urticaria

Sarah Denman, MPharm[a], Kate Ford[a], John Toolan[a], Anoop Mistry, MD[a] , Claire Corps, PhD[a], Philip Wood, PhD[a], Sinisa Savic, PhD[a,b*]

[a]Department of Clinical Immunology and Allergy, St James's University Hospital, Beckett Street, Leeds, UK

[b]National Institute for Health Research–Leeds Musculoskeletal Biomedical Research Unit (NIHR-LMBRU) and Leeds Institute of Rheumatic and Musculoskeletal Medicine (LIRMM), Wellcome Trust Brenner Building, St James's University Hospital, Beckett Street, Leeds, UK

[*]Corresponding author:
Sinisa Savic MD, PhD Department of Clinical Immunology and Allergy, National Institute for Health Research–Leeds Musculoskeletal Biomedical Research Unit (NIHR-LMBRU) and Leeds Institute of Rheumatic and Musculoskeletal Medicine (LIRMM), Wellcome Trust Brenner Building, St James University, Beckett Street, Leeds, LS9 7TF, UK
Email: s.savic@leeds.ac.uk Tel: +441132065567, Fax: +441132067250

To the Editor,

Omalizumab is an anti-IgE monoclonal antibody, which is licensed as add-on therapy for chronic spontaneous urticaria (CSU)[1]. Although it provides effective symptomatic control, omalizumab does not always induce lasting remission and many patients require repeated courses.

Between August 2010 and July 2016 we treated 123 CSU patients with omalizumab. Only 5% (n=6) have stopped omalizumab after achieving remission (1.6% [n=2] after one course only). Of our current cohort, 75% have had >1 treatment course.

Due to perceived risk of anaphylaxis it is recommended that omalizumab is administered by a healthcare professional and treatment for anaphylaxis be available[1]. However, the reported prevalence of anaphylaxis in omalizumab treated asthma patients is very low (0.1%)[1]. Within CSU patients, none of the 3 pivotal trials reported omalizumab-induced anaphylaxis[2,3,4]. There have been few cases reports subsequently and in these it is hard to determine if true anaphylaxis or a CSU flare. Up to July 2016 we have administrated 1880 doses of omalizumab to CSU patients and had no reported cases of treatment-associated anaphylaxis.

The increasing number of patients requiring repeated courses of omalizumab for CSU put significant pressure on our nursing capacity. Considering the low-reported prevalence of anaphylaxis, our own experience and patient preference we proposed a home treatment pathway. Our pharmacy risk management group approved this proposal. This treatment pathway can be seen in Figure 1.

Specific patient consent and competency assessment paperwork have been designed and all patients are trained and supplied with adrenaline auto-injectors.

We have a current active cohort of 97 patients and the longest treatment period is 70 months. There are 70% (n=68) on home treatment. Duration of home treatment ranges from 1 to 19 months (average 7 months, median 7 months). The number of doses administered in hospital before transfer to home ranges from 2 to 45 (average 11; median 7).

There have been no cases of anaphylaxis or other serious adverse effects in those patients treated at home and no patient on home treatment has subsequently transferred back to hospital. Patients report a preference to home treatment as it has a lower impact on their daily living, which subsequently has a positive impact on their quality of life. Adherence (self-reported) in home treatment patients appears to be excellent.

In conclusion, home treatment of omalizumab is a safe, cost-effective pathway that is preferred by patients and increases capacity to provide this treatment for a growing number of patients.

References:

1. Summary of Product Characteristics: Xolair®, Novartis Pharmaceuticals UK Ltd 14/04/2016. Accessed via www.medicines.org.uk on 23/05/2016.

2. Saini SS, Bindslev-Jenson C, Maurer M, Grob JJ, Bülbül Baskan E, Bradley MS, Canvin J, Rahmaoui A, Georgiou P, Alpan O, Spector S, Rosén K. Efficacy and safety of omalziumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study. J Invest Dermatol 2015; 135: 67-75.

3. Maurer M, Rosén K, Hsieh HJ, Saini S, Grattan C, Gimenéz-Arnau A, Agarwal S, Doyle R, Canvin J, Kaplan A, Casale T. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med 2013; 368: 924-935.

4. Kaplan A, Ledford D, Ashby M, Canvin J, Zazzali JL, Conner E, Veith J, Kamath N, Staubach P, Jakob T, Stirling RG, Kuna P, Berger W, Maurer M, Rosén K. Efficacy and safety of omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticarial despite standard combination therapy. J Allergy Clin Immunol 2013; 132: 101-109.

Figure 1: The Leeds Teaching Hospitals NHS Trust Protocol for Omalizumab for Chronic Spontaneous Urticaria