ADAPT: Final research report

Study title:	The role of anti-IgE (omalizumab) in the management of severe recalcitrant paediatric atopic eczema
REC reference:	11/LO/0123
Protocol number:	ADAPT
EudraCT number:	2010-020841-29
IRAS project ID:	48144

Research objective:

Our primary research objective was to assess if anti-IgE can improve very severe eczema in children who have not responded to the usual treatments for eczema, as compared to placebo.

Study findings:

The following are our study findings and how we achieved our objectives.

Background: Childhood atopic dermatitis (AD) is common but there is limited evidence for management when topical therapy fails.

Methods: A 24-week randomised double-blind placebo-controlled trial of omalizumab (anti-IgE) in atopic children with severe AD (objective SCORing Atopic Dermatitis, SCORAD >40), unresponsive to optimum topical or systemic therapy.

Results: 62 children with a median baseline total IgE of 8,373 IU/l, received omalizumab or placebo (1:1). The 24 week adjusted mean difference in oSCORAD between arms was -6.9 (95%CI -12.2, -1.5; p=0.013) in favour of omalizumab. This was reflected in 2 other objective AD severity scores.

Improved quality of life (QoL) scores were also seen in the omalizumab arm for both the (C)DLQI (-3.5, 95%CI [-6.4, -0.5]; p=0.022) and PADQLQ (-0.5, 95%CI [-0.9, -0.0]; p=0.050).

Improvements were seen despite lower potent topical steroid use in the omalizumab-treated arm compared to placebo, median 109 vs 161 days (p=0.067) and 15.5% vs 30.9% body surface area coverage.

Seven serious adverse events occurred in six patients in both arms.

Conclusions: This is the first randomised controlled trial to show omalizumab significantly reduced AD severity, and improved QoL in an atopic paediatric population with severe AD. The oSCORAD average within-arm reduction for omalizumab exceeded the minimum clinically important difference. This in the context of highly elevated total IgE levels, outside recommended prescribing guidelines, and despite a reduction in potent topical steroid use. These results suggest omalizumab may be a treatment option for difficult-to-manage, highly atopic children with severe eczema.

Dissemination of findings:

1. Final report submitted to the NIHR (National Institute for Health Research)
2. Original article submitted to the New England Journal of Medicine
3. Invited to present our findings at the British Society of Allergy and Clinical Immunology Annual meeting 2018
4. Once publication had been confirmed, we will be feeding back to participants.