Prematurely ended - Statement

EudraCT Number:	*2011-003746-41*
Full title of the study:	*A two-center, double blind, placebo-controlled study in parallel design to assess the efficacy and safety of 150 and 300mg omalizumab in subjects with antihistamine-resistant cold contact urticaria (CCU)*
Abbreviated title:	CUTEX
Sponsor-ID:	*CIGE025EDE14T*
Sponsor:	Charité – Universitätsmedizin Berlin
Contact email address:	martin.metz@charite.de
Product:	*Omalizumab (Xolair, Novatis Pharma, UK)*
Study Contact:	*Prof. Dr. Martin Metz* *Klinik für Dermatologie, Allergologie und Venerologie,* Charité-Universitätsmedizin
Date of early termination:	*11.02.2015*
Statement:	*The study was terminated early because investigators from all three sites involved in the study suspected that the two verum groups showed a significant response and the placebo group did not. Therefore, a blinded analysis of the available study data of all 31 completed patients was performed which confirmed the suspicion.*

Publication Reference:

Full title of the trial: *A two-center, double blind, placebo-controlled study in parallel design to assess the efficacy and safety of 150 and 300mg omalizumab in subjects with antihistamine-resistant cold contact urticaria (CCU)*

Publication title: Omalizumab is effective in cold urticaria—results of a randomized placebo-controlled trial

Publication*:* J Allergy Clin Immunol, 2017, 140:864-867

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