ALLERGY, ASTHMA & CLINICAL IMMUNOLOGY

POSTER PRESENTATION Open Access

Fast 3: a phase III randomized double-blind, placebo-controlled multicenter study of Icatibant for subcutaneous injection in patients with acute Attacks of Hereditary Angioedema (HAE)

B Ritchie

From Canadian Society of Allergy and Clinical Immunology Annual Scientific Meeting 2009
Halifax, Canada. 22-25 October 2009

Background

Herditary Angioedema (HAE) is a rare disorder (1:10,000 – 1:50,000) characterized by episodic, localized edema of skin or mucosa of airway, genitourinary tract or gastrointestinal tract. It is due to inherited deficiency of the serpin known as C1 Inhibitor leading to unopposed kallikrein, producing excess bradykinin which binds to G-protein coupled receptors known as B1 and B2 receptors. Icatabant, a ten amino acid peptide analogue of bradykinin is an effective blocker of the B2 receptor and has been shown to provide rapid and complete relief of symptoms compared to Tranexamic acid (Fast-1) or placebo (Fast-2). Rapid relief of laryngeal edema was confirmed in the open label arm. A new trial (Fast-3) has begun. Primary Objective are to compare icatibant vs placebo on the time to symptom relief using a 3 symptom Visual Analog Scale (VAS) score during moderate to very severe acute cutaneous and/or abdominal attacks in patients with type I or type II hereditary angioedema (HAE). Secondary Objectives are to compare the global outcome following treatment with icatibant vs placebo using patient-reported (single symptom and 8 symptom composite score) and physician-reported outcome measures at 4 and 8 hours; to compare the time to almost complete symptom relief following treatment with icatibant vs placebo during moderate to very severe acute cutaneous and/or abdominal attacks; to assess safety and tolerability of icatibant vs placebo; and to assess the efficacy and safety of open-label icatibant treatment in patients experiencing laryngeal edema attacks. 88 patients, aged 18 or older, with an attack of at least moderate severity os skin, abdomen or larynx/pharynx will be randomized to double-blind treatment with either 30 mg of Icatabant SC or placebo.

Published: 12 May 2010

doi:10.1186/1710-1492-6-S1-P27
Cite this article as: Ritchie: Fast 3: a phase III randomized double-blind, placebo-controlled multicenter study of Icatibant for subcutaneous injection in patients with acute Attacks of Hereditary Angioedema (HAE). *Allergy, Asthma & Clinical Immunology* 2010 **6**(Suppl 1):P27.

Correspondence: bruce.ritchie@ualberta.ca
4-71 MSB, University of Alberta, Edmonton, AB, Canada T6G 2B7