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Short paper

Serum trough infliximab levels: A comparison of three different immunoassays for the monitoring of CT-P13 (infliximab) treatment in patients with inflammatory bowel disease

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ABSTRACT

Background: CT-P13 is a biosimilar drug of reference infliximab and is approved in some countries for use in some indications for which reference infliximab is approved, including inflammatory bowel disease (IBD). The CT-P13 formulation is identical to that of reference infliximab and has similar physicochemical characteristics. However, even a small molecular distinction could lead to different behavior of CT-P13 in immunoanalytical detection systems.

Aim: To determine the correlation between three different enzyme-linked immunosorbent assays for infliximab detection in the measurement of CT-P13 trough serum levels.

Methods: Serum samples (n = 42) from IBD patients (n = 22) treated with CT-P13 Remsima™ (Celltrion, Korea) were evaluated in a blinded way in infliximab assays manufactured by (A) Matriks Biotek (Turkey), (B) Theradiag (France), and (C) R-Biopharm (Germany).

Results: All assays showed excellent qualitative correlation (Cohen's kappa = 0.90 for A vs. B, 0.76 for A vs. C, and 0.83 for B vs. C). A linear quantitative correlation was satisfactory as well (Spearman's r = 0.91 for A vs. B, 0.86 for A vs. C and 0.92 for B vs. C). Assay C did not detect CT-P13 in 6 samples detected by A and/or B.

Conclusion: There is a good correlation of CT-P13 serum level detection between these assays.

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1. Introduction

CT-P13 is a biosimilar monoclonal antibody infliximab for the treatment of patients with autoimmune diseases such as inflammatory bowel disease (IBD) [1–3]. Generally, biosimilars are biological products showing high resemblance to the reference biological products, and they exhibit no clinically meaningful differences in terms of safety and effectiveness [4]. Only minor differences in clinically inactive components are allowable in

biosimilars compared to reference products. It is expected that the spread of biosimilar monoclonal antibodies will lead to cost savings in healthcare budgets and might also improve the availability of the biological treatment for patients [5–8].

However, even a small difference in the molecular structure can lead to different behaviors of the biosimilar drug in analytical systems for the detection of serum drug levels [9]. Today, the main commercially available assays for determining serum trough levels of infliximab (IFX) are enzyme-linked immunosorbent assays (ELISAs), from those that are relatively inexpensive and easy to perform to more sophisticated and costly detection systems. The main objective of this study was to compare three ELISAs for the detection of serum infliximab trough levels in patients with CT-P13 (Remsima) treatment: SHIKARI Q-Inflixix (Matriks Biotek, Turkey), LISA-Tracker Duo Infliximab (Theradiag, France), and RIDASCREEN

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