Serum Levels of Infliximab Biosimilar in a Child Delivered From a Mother Treated for Ulcerative Colitis

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Lay Summary

The infliximab biosimilar CT-P13 is used for the treatment of ulcerative colitis. We report for the first time the serum drug levels and long-term health status of the child of a patient treated with CT-P13 throughout her pregnancy.

Key Words: ulcerative colitis, biosimilar, pregnancy

Abbreviations: IFX: infliximab; UC: ulcerative colitis

Introduction

Pregnancy in patients with clinically active ulcerative colitis (UC) is associated with risks,[1] and it is recommended for UC patients who conceive to continue their medication.[2]

Clinical studies of CT-P13, an infliximab (IFX) biosimilar, have excluded pregnant women; therefore the safety profile during pregnancy can only be extrapolated from that of IFX. We report a case where CT-P13 was maintained for a patient throughout her pregnancy, and describe for the first time the serum CT-P13 levels of the child born, as well as the lack of significant adverse events up to the age of five.

ratio of cord blood to maternal drug concentration at birth was 2.74. The serum CT-P13 level of the infant was measured regularly (Figure 1), showing a marginally detectable drug level at week 40 which was undetectable by week 47. Apart from a mild bronchial asthma which is under control, the child has remained healthy throughout the first 5 years of life with no episodes of severe infection. The child received all the recommended routine immunizations, apart from the rotavirus vaccine. The Bacille Calmette-Guérin (BCG) vaccine was given at 1 year, after confirming that serum level of CT-P13 was undetectable.