INTRODUCTION

NA25220 study design.

WA22762 study design.

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- To identify covariate factors that may influence TCZ disposition
- BRIEFTAC (SUMMACTA) and NA25220 (BREVACTA) identify covariate factors that may influence TCZ disposition

OBJECTIVES

- To establish a population PK model that describes the PK of TCZ after IV and SC administration
- To describe factors associated with high and low TCZ concentrations
- To determine whether the presence of concomitant therapy (e.g., DASL antibodies) affects the PK of TCZ after IV and SC administration
- To perform model-based simulations of virtually intended dosing regimes

METHODS

- PK data from two phase 3 studies, WA27262 (n = 550) and NA25220 (n = 200), were analyzed using NONMEM 7.2.0

RESULTS

- The final IV model included the effects of weight and height, weight on clearance
- The final SC model included the effects of weight, height, and log (weight) on the SC disposition parameters

CONCLUSIONS

- TCZ clearance increased with body weight. As a result, for weight-based dosing of 8 mg/kg IV Q4W, steady-state Cmean was lower (51.3 vs 152.7 μg/mL) after QW SC dosing
- Differences in volume of distribution were more notable between the IV and SC dosing, reflecting the higher volume of distribution of IV dosing
- TCZ clearance increased with body weight, resulting in a higher volume of distribution after QW SC dosing
- Dosing of 162 mg SC QW in patients weighing >60 kg compared with the mean Cmean for patients weighing 60 to 100 kg. For the 162 mg SC Q2W regimen, the volume of distribution was larger in patients weighing >60 kg, resulting in lower Cmean values.

REFERENCES

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