PHARMACOKINETICS, EXPOSURE–RESPONSE RELATIONSHIPS, AND IMMUNOGENICITY IN CROHN'S DISEASE PATIENTS WITH USTEKINUMAB SECONDARY LOSS OF RESPONSE FOLLOWING USTEKINUMAB IV RE-INDUCTION: RESULTS FROM THE WEEK 16 ANALYSIS OF THE POWER STUDY

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The POWER study evaluated pharmacokinetics, exposure-response relationships, and immunogenicity of intravenous re-induction versus continued subcutaneous ustekinumab in Crohn's disease patients with secondary loss of response to maintenance therapy through 16 weeks.

KEY POINTS

- Adult Crohn's disease patients with secondary loss of response to standard subcutaneous ustekinumab maintenance were randomized to receive either ~6mg/kg IV ustekinumab or 90mg subcutaneous ustekinumab at week 0, followed by 90mg subcutaneous maintenance at weeks 8 and 16.
- Median serum ustekinumab concentrations at weeks 8 and 16 were higher in the IV arm compared to the subcutaneous arm, with 63.9% of IV patients versus 41.1% of subcutaneous patients achieving trough concentrations ≥1.3µg/mL at week 16.
- The proportion of patients achieving clinical response at week 16 was similar between arms in the ≥1.3µg/mL trough concentration group, with no clear exposure-response relationship for clinical response observed.
- Quartile analysis showed a relationship between increased exposure in the IV arm and endoscopic remission, with more IV patients achieving endoscopic remission compared to the subcutaneous arm, particularly in higher quartile groups.

– Incidence of anti-drug antibodies through week 16 was low at 0.93% overall, with 2 patients in the subcutaneous arm and 0 in the IV arm.

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