MRI Results Following Discontinuation of Methotrexate in Patients With Rheumatoid Arthritis Treated With Subcutaneous Tocilizumab: Results From a Randomized Controlled Trial

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BACKGROUND
Previous studies have shown that tocilizumab (TCZ) in combination with methotrexate (MTX) is as effective as MTX monotherapy in patients with rheumatoid arthritis (RA). This study evaluated the effects of discontinuing MTX compared to continuing MTX in patients with active RA.

OBJECTIVE
To evaluate the effects of discontinuing MTX compared to continuing MTX on MRI outcomes in patients with active RA.

METHODS
Study Design
- COMP-CTR-201: randomized, double-blind, placebo-controlled 52-week study (day 0 week 52; week 48 to week 52 followed-up to week 60).
- Patients with an inadequate response to MTX were randomized 1:1 to receive TCZ mono or continue TCZ + MTX at week 24.
- Both hands and wrists were imaged with a 1.5-T MRI at Weeks 24 and 40 (no imaging was performed at Week 0).
- Patients were required to have an inadequate response to MTX.

RESULTS
Baseline Demographics and Clinical Characteristics
- Patients were stratified by disease activity at Week 0 (n = 38).
- Baseline demographics and clinical characteristics were similar between treatment groups.
- MRI scores at Week 24 were similar between treatment groups.

Statistical Methods
- Baseline MRI scores from the ACTRIO study were established to establish that 120 patients per group would provide 90% power to detect 30% differences in baseline MRI score (Week 0). To detect a difference of 10% between Week 24 and Week 40, 300 patients were required.
- The MRI score was calculated as the sum of the individual scores for bone erosion and cartilage loss.

CONCLUSION
- Discontinuing MTX was associated with a reduction in MRI progression compared to continuing MTX.
- The majority of patients who discontinued MTX had a significant reduction in bone erosion and cartilage loss at Week 40.

REFERENCES

DISCLOSURES
- The majority of patients who failed to progress in MRI score at Week 24 had a reduction in bone erosion and cartilage loss at Week 40.
- Differences between the groups in the proportion of patients with progression in each outcome were not statistically significant.

Figure 1. Objectives and Endpoints
- MRI results following discontinuation of methotrexate in patients with rheumatoid arthritis treated with subcutaneous tocilizumab.

Table 1. Baseline MRI Scores and Clinical Characteristics
- Baseline MRI scores were similar between treatment groups.

Figure 2. Baseline MRI Scores
- Baseline MRI scores were similar between treatment groups.

Figure 3. Change From Week 24 to Week 40
- MRI scores decreased from Week 24 to Week 40 in both treatment groups.

Figure 4. Scatter Plots for Bone Erosion and Cartilage Loss
- There were no significant differences in bone erosion and cartilage loss between treatment groups.

Figure 5. Cumulative Probability Plots
- Cumulative probability plots showed no major outliers for change greater than SDC in erosion, synovitis, and osteitis.

Figure 6. Flowchart of Study Design
- Flowchart of the study design for the discontinuation of methotrexate in patients with RA.

Table 2. MRI Scores at Randomization (Week 0)
- Baseline MRI scores were similar between treatment groups.

Table 3. MRI Scores at Discontinuation (Week 40)
- MRI scores decreased from Week 24 to Week 40 in both treatment groups.

Table 4. Baseline MRI Scores and Clinical Characteristics
- Baseline MRI scores were similar between treatment groups.

Figure 7. Change From Week 24 to Week 40
- MRI scores decreased from Week 24 to Week 40 in both treatment groups.

Figure 8. Flowchart of Study Design
- Flowchart of the study design for the discontinuation of methotrexate in patients with RA.