37° SBR 2020
Congresso
Brasileiro de Reumatologia

Promoção
70 anos Sociedade Brasileira de Reumatologia

Realização
SOCIEDADE PAULISTA DE REUMATOLOGIA

https://doi.org/10.47660/CBR.2020.17515

EARLIER TREATMENT OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS WITH CERTOLIZUMAB PEGOL RESULTS IN IMPROVED CLINICAL AND PATIENT-REPORTED OUTCOMES

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BACKGROUND

Certolizumab pegol (CZP) improves symptoms of nonradiographic axial spondyloarthritis (nr-axSpA), which is unknown if earlier treatment improves efficacy. We report clinical and patient-reported outcomes (PROs) in patients with active nraxSpA over 52 weeks by baseline symptom duration.

MATERIALS AND METHODS

C-axSpAnd (NCT02552212) is a 3-year, phase 3 study including a 52week double-blind, placebo-controlled period (completed). Patients had inadequate response to ≥ 2 nonsteroidal anti-inflammatory drugs (NSAIDs) and were randomized 1:1 to CZP (400 mg at week 0/2/4, then 200 mg every two weeks) or placebo. Outcomes are reported by baseline symptom duration (< 5 / ≥ 5 years, < 3 / ≥ 3 years). For binary measures, patients with values missing/observed after discontinuing double-blind study treatment were considered non-responders. For quantitative measures, last observation from double-blind treatment was carried forward.

RESULTS

One hundred fifty-nine of 317 patients were randomized to CZP, and 158/317 to placebo. The median (range) baseline symptom duration was 4.9 years (1.0–41.9 years) for CZP and 5.2 years (1.1–38.2 years) for placebo-treated patients; 50.3% (80/158) CZP and 48.7% (77/158) placebo patients had a symptom duration < 5 years. Responder rates were substantially better among CZP-treated patients with symptom duration < 5 vs ≥ 5 years at baseline for ASDAS-MI at week 12 (46.3% [37/80] vs 24.1% [19/79]) and week 52 (55.0% [44/80] vs 39.2% [31/79]), and for ASAS40 (week 12: 58.8% [47/80] vs 36.7% [29/79]; week 52: 65.0% [52/80] vs 48.1% [38/79]). Greater improvements in BASDAI were also observed in CZP-treated patients with < 5 vs ≥ 5 years symptom duration, and in PROs such as fatigue (mean [SD; n]: baseline: 7.1 [1.5; 80] vs 7.2 [1.7; 79]; week 52: 3.3 [2.7; 79] vs 4.1 [2.7; 78]) and SF-36 PCS (baseline: 35.0 [7.1; 80] vs 34.2 [7.0; 77]); week 52: 47.6 [8.9; 79] vs 42.1 [9.4; 78]). Amongst placebo patients, responses were low and there was no consistent trend by symptom duration for ASDAS-MI (week 12: 9.1% [7/77] vs 3.7% [3/81]; week 52: 7.8% [6/77] vs 6.2% [5/81]), ASAS-40 (week 12: 11.7% [9/77] vs 11.1% [9/81]; week 52: 18.2% [14/77] vs 13.6% [11/81]), and for BASDAI and PROs. At week 52, ASDAS-MI responder rates were greater in CZP-treated patients with < 3 vs ≥ 3 years symptom duration (56.4% [31/55] vs 42.3% [44/104]). ASAS40 was achieved by 65.5% (36/55) vs 51.9% (54/104) CZP patients.

CONCLUSION

Certolizumab pegol-treated nr-axSpA patients with shorter symptom duration showed greater improvements in signs and symptoms of disease. To our knowledge, this is the first report indicating benefits of early CZP treatment for nr-axSpA.

REFERENCE

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