Clinical: MOZArT

(Management of Osteoarthritis of the Knee with Zeel®and Traumeel Injections[10])

Efficacy of co-administered IA injections of Traumeel® and Zeel® Injection Solutions vs. placebo (saline IA injections) in the management of moderate to severe pain associated with knee OA.[10]

Study Design: Double-blind, randomized, multicenter (30 USA sites), placebo-controlled study. Study design was supervised by Dr. Roland W. Moskowitz of University Hospital Cleveland, Ohio, and Dr. Carlos Lozada of University of Miami Health: System, Rheumatology.

Objective: Compare the efficacy of IA injections of Traumeel® and Zeel® Injection Solutions versus placebo (saline IA injections) in the management of moderate to severe pain associated with knee OA.

Methods: In this multicenter, double-blind, randomized, controlled trial, 232 patients with moderate to severe chronic knee OA were randomized to three weekly IA injections of either combined Traumeel® and Zeel® Injection Solutions or saline by clinical investigators experienced with use of the IA injection route.

Outcome Measures:

- The primary efficacy variable was change in knee pain from baseline to end of study (week 17) as measured by the WOMAC OA Pain Subscale (Section A, 1–5) 100 mm VAS. Secondary measures included total WOMAC score and sub-scores for stiffness (B); physical function (C); change in pain following a 50-foot walk (100 mm VAS); and patient and physician global assessments.

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Clinical Results

Primary End Points

Combined IA injections of Traumeel® and Zeel® Injection Solutions provided statistically significant and clinically relevant pain relief on days 15 to 99 in comparison to placebo. In this double-blind, randomized, controlled trial, the Traumeel® and Zeel® injection combination was shown to be a safe and effective treatment for pain in moderate to severe knee OA.

Significant + Relevant Pain Relief: WOMAC Scores

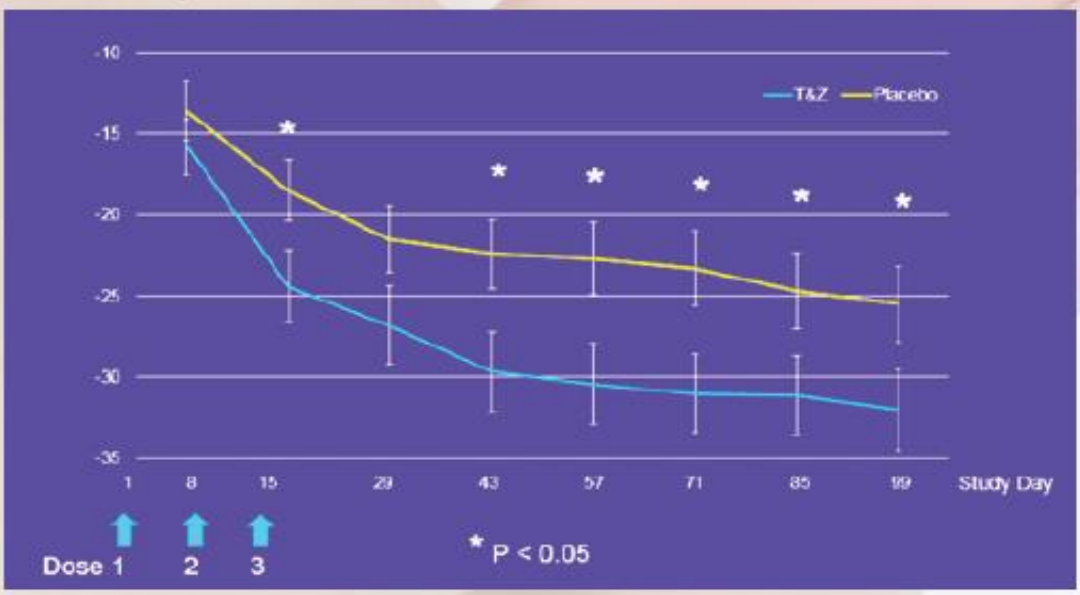

Figure: Mean WOMAC A (Pain) changes from baseline. Solutions did not discriminate for WOMAC A pain as expected after only 1 of 3 injections on day 8 (p = 0.3715), but subsequently were significantly different (p = 0.05) on days 15, 43, 57, 71, 85 and 99 (primary end point day), and approached significance on day 29 (p = 0.0686)

[10]To read the study abstracts which were presented by Dr. Carlos Lozada to the American College of Rheumatology and the European League Against Rheumatism (EULAR), visit...
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