Figure 2. Bootstrapped mean oral morphine equivalent dose per person per year for patients with inflammatory arthritis (above) and age and sex matched comparators (below). Box edges represent 25-75th percentiles and whiskers 95% confidence intervals.

Table 1. Baseline demographic data. Mean $\pm$ SD unless specified. * defined from diagnosis to baseline.

	All patients	Rheumatoid arthritis	Psoriatic arthritis	Ankylosing spondylitis	Undifferentiated arthritis
Total n (%)	940 (100)	359 (38)	251 (27)	217 (23)	113 (12)
Age (years)	49 $\pm$ 14	53 $\pm$ 14	49 $\pm$ 13	43 $\pm$ 13	44 $\pm$ 15
Disease duration (years)*	7.8 $\pm$ 8.5	8.2 $\pm$ 8.2	7.4 $\pm$ 7.8	8.3 $\pm$ 10.2	6.3 $\pm$ 6.6
Female	58%	73%	59%	34%	52%

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OP0089 EFFICACY OF CLOMIPRAMINE FOR CHRONIC LUMBAR RADICULAR PAIN A RANDOMIZED CLINICAL TRIAL

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Background: Lumbar radicular pain is the most common chronic neuropathic pain syndrome. Antidepressants are highly recommended for neuropathic pain, but there is no evidence for their efficacy.

Objectives: The aim of this double-blind, randomised, placebo-controlled trial is to determine whether Clomipramine (an antidepressant) is more effective than placebo in reducing pain in individuals with resistant chronic lumbar radicular pain.

Methods: A double-blind, randomized, clinical trial. Sixty-two patients with resistant chronic lumbar radicular pain were included. (The sample size was calculated on the assumption that clomipramine would reduce the incidence of lumbar radicular pain of 35%, compared with placebo, with a two-sided test, an alpha level of 0.05, and a power of 85%). Patients were randomly allocated to receive either Clomipramine by slow intravenous infusion for 10 days in a hospital setting with progressively increasing doses, 25mg on the first day, 50mg on the second day and 75mg on the third day until the tenth day, or placebo (500ml of physiological serum a day). For both groups, paracetamol is added intravenously at a dose of 3g per day for ten days, Parecoxib for 3 days and ten sessions of lumbar spine rehabilitation including analgesic massage, muscle strengthening and joint maintenance. At the exit, clomipramine was relayed with 25mg per day orally until the 90th day for

clomipramine group, and paracetamol was authorized in both groups, in case of severe pain. The primary outcome was pain intensity, measured at baseline, 5th day, 10th day and 90th day using VAS pain (10mm). Secondary outcome included DN4-questionnaire, lumbar radicular discomfort (VAS 10mm), pain-free perimeter of walking (min), disability assessed using the Roland Morris Disability questionnaire and severity of mood symptoms assessed using the Hospital Anxiety and Depression scale (HAD), measured on days 0, 5, 10 and 90.

Results: 31 patients were assigned to the clomipramine group and 31 to the placebo group. There were no differences between the groups in demographic characteristics. Treatment by Clomipramine had a significantly greater reduction in pain, discomfort and DN4 from the 5th day ($p = 0.000$, $p = 0.001$ and $p = 0.004$ respectively) than the placebo, with an improvement maintained until 90th day. There was a statistically significant improvement in pain-free walking distance and disability for the clomipramine group from the 10th day ($p = 0.02$ and 0.001 respectively) and that maintained until 90th day. However, there was no significant improvement in HAD between the 2 groups. ($p \geq 0.1$).

Conclusion: This double-blind, randomized, clinical trial shows that clomipramine is quickly effective and maintained over time in the management of resistant chronic lumbar radicular pain. It can therefore be part of the therapeutic arsenal in this sense.

Disclosure of Interests: None declared

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OP0090 EFFICACY OF SUBCUTANEOUS TANEZUMAB FOR THE TREATMENT OF CHRONIC LOW BACK PAIN: AN ANALYSIS OF BRIEF PAIN INVENTORY-SHORT FORM SCORES FROM A 56-WEEK, RANDOMIZED, PLACEBO- AND TRAMADOL-CONTROLLED, PHASE 3 TRIAL

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Background: Tanezumab, a monoclonal antibody against nerve growth factor, was recently evaluated in an 80 week placebo and tramadol-controlled trial in patients with chronic low back pain (CLBP) and a history of inadequate response to standard-of-care analgesics (NSAIDs, opioids, etc). Primary endpoint was change in Low Back Pain Intensity (LBPI) at week 16 vs placebo. Key secondary endpoints were the proportion of patients with $\geq 50\%$ improvement in LBPI at week 16, change in Roland Morris Disability Questionnaire score at week 16, and change in LBPI at week 2 (all vs placebo). Tanezumab 10mg met the primary and all key secondary endpoints. Tanezumab 5mg did not meet the primary endpoint, but improved 2 of 3 key secondary endpoints. Due to the primary endpoint result and the statistical gate-keeping approach to control for multiple comparisons, a conclusion of superiority over placebo could not be made for the 5mg dose.

Objectives: To further characterize tanezumab's effects on pain and function in this trial through analysis of Brief Pain Inventory-short form (BPI-sf) scores.

Methods: Patients received placebo (n=406), subcutaneous (SC) tanezumab 5mg (every 8 weeks; n=407), SC tanezumab 10mg (every 8 weeks; n=407) or oral tramadol prolonged-release (100-300mg/day; n=605). Pre-specified secondary endpoints included BPI-sf worst pain, average pain, the overall pain interference index, and selected individual domains of the index (general activity, walking ability, sleep, and normal work). Least squares (LS) mean (standard error [SE]) changes from baseline in BPI-sf scores were compared between groups (unadjusted for multiplicity) at week 16 using an analysis of covariance model. Scores range from 0-10 with higher scores indicating greater pain severity or functional impairment.

Results: LS mean (SE) differences from placebo for worst pain were -0.52 (0.19) for tanezumab 5mg ($p \leq 0.01$), -0.54 (0.19) for tanezumab 10mg (≤ 0.01), and -0.24 (0.17) for tramadol ($p=0.17$). LS mean (SE) differences from placebo for average pain were -0.37 (0.18) for tanezumab 5mg ($p=0.04$), -0.46 (0.18) for tanezumab 10mg (≤ 0.01), and -0.17 (0.16) for tramadol ($p=0.29$). LS mean (SE) differences from placebo for the pain interference index were -0.41 (0.18) for tanezumab 5mg ($p=0.03$), -0.58 (0.18) for tanezumab 10mg (≤ 0.01), and -0.15 (0.17) for tramadol ($p=0.39$). Effects of tanezumab were not statistically different ($p > 0.05$)