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Ενδιαφέροντα Άρθρα Βιβλιογραφίας

Efficacy and safety of the selective co-stimulation modulator abatacept following 2 years of treatment in patients with rheumatoid arthritis and an inadequate response to anti-tumor necrosis factor therapy.

Genovese MC, Schiff M, Luggen M, et al.
Ann Rheum Dis 2008;67:547-54

Ασθενείς με ρευματοειδή αρθρίτιδα και ανεπαρκή ανταπόκριση σε θεραπεία με αντι-TNF παράγοντα που έλαβαν στη συνέχεια το τροποποιητικό του Τ λεμφοκυττάρου abatacept εμφάνισαν ύφεση (DAS28<2.6) σε ποσοστό 11.1% στους 6 μήνες θεραπείας και 20,3% στα 2 έτη της θεραπείας.

Objective: To evaluate the safety and efficacy of abatacept during 2 years of the ATTAIN (Abatacept Trial in Treatment of Anti-TNF INadequate responders) trial in patients with rheumatoid arthritis.

Methods: Patients completing the 6-month, double-blind period were eligible to enter the long-term extension; patients received abatacept ~10 mg/kg, plus disease-modifying antirheumatic drugs. Safety and efficacy (American College of Rheumatology (ACR) criteria responses, DAS28 (C-reactive protein), HAQ-DI, SF-36, Medical Outcomes Study Sleep Problems Index, fatigue VAS) were assessed through 2 years.

Results: 317 patients (218 from the abatacept and 99 from the placebo group) entered and 222 (70%) completed 18 months of long-term extension treatment. The incidence and type of adverse events were consistent between the double-blind and cumulative (double-blind plus long-term extension) periods. Rates of serious adverse events were 25.6 and 23.4 per 100 patient-years in the double-blind versus cumulative period. At 6 months and 2 years, using non-responder analyses, ACR responses in abatacept-treated patients were: ACR 20, 59.4% and 56.2%; ACR 50, 23.5% and 33.2%; ACR 70, 11.5% and 16.1%; HAQ-DI responses were 54.4% and 47.9%. At 6 months and 2 years, using post-hoc as-observed analyses, the percentage of patients (95% confidence interval) achieving DAS28 (C-reactive protein) low disease activity score (≤ 3.2) and DAS28 (C-reactive protein)-defined remission (<2.6) increased from 18.3% (13.0, 23.5) to 32.0% (24.6, 39.4) and 11.1% (6.8, 15.3) to 20.3% (13.9, 26.6). Clinically meaningful improvements in SF-36, pain, fatigue and sleep problems were also maintained throughout the 2 years of abatacept treatment.

Conclusion: No unique safety observations were reported during open-label exposure. Improvements in the signs and symptoms of rheumatoid arthritis, physical function and health-related quality of life observed after 6 months, were maintained throughout the 2 years in this population with difficult-to-treat disease.

Interleukin-1 receptor antagonist (anakinra) treatment in patients with systemic-onset juvenile idiopathic arthritis or adult onset Still disease: preliminary experience in France.

Lequerré T, Quartier P, Rosellini D, et al.
Ann Rheum Dis 2008;67: 302-8

Το kineret είναι αποτελεσματικό στη νόσο

Still των ενηλίκων αλλά όχι στη νεανική ιδιοπαθή αρθρίτιδα συστηματικής μορφής

Background: Anakinra treatment has been reported to be effective in some patients with systemic-onset juvenile idiopathic arthritis (SoJIA) or adult-onset Still disease (AoSD). Objectives: To assess the efficacy and the safety of anakinra treatment in SoJIA and AoSD.

Methods: SoJIA and AoSD patients were treated with anakinra (1–2 mg/kg/day in children, 100 mg/day in adults); we analysed its effect on fever, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels, numbers of swollen and tender joints, the assessment of disease activity (by physician and parent/patient) and pain (by parent/patient), and American College of Rheumatology (ACR) pediatric core set criteria for JIA activity.

Results: A total of 35 patients were included, 20 with SoJIA and 15 with AoSD. Their mean age (range) at the onset of treatment was 12.4 (3–23) and 38.1 (22–62) years, respectively; disease duration was 7.0 (1–16) and 7.8 (2–27) years, respectively. Active arthritis was present in all cases but one. Of the 20 SoJIA patients, 5 achieved ACR 50% improvement in symptoms (ACR50) response criteria at 6 months. Steroid dose had been decreased by 15% to 78% in 10 cases. A total of 11 of the 15 AoSD patients achieved at least a 50% improvement for all disease markers (mean follow-up: 17.5 (11–27) months). Steroids had been stopped in two cases and the dose was decreased by 45% to 95% in 12 patients. Two patients stopped anakinra due to severe skin reaction, and two patients due to infection: one visceral leishmaniasis and one varicella.

Conclusion: Anakinra was effective in most AoSD patients, but less than half SoJIA patients achieved a marked and sustained improvement.

Etanercept Treatment for Children and Adolescents with Plaque Psoriasis.

Paller AS, Siegfried EC, Langley RG, et al.

N Eng J Med 2008;358:241-51

Το Etanercept βελτιώνει σε σημαντικό βαθμό τη βαρύτητα της μέτριας ως σοβαρού βαθμού ψωρίαση κατά πλάκας σε παιδιά και εφήβους

Background: Etanercept, a soluble tumor necrosis factor receptor, has been shown to lessen disease severity in adult patients with psoriasis. We assessed the efficacy and safety of etanercept in children and adolescents with moderate-to-severe plaque psoriasis.

Methods: In this 48-week study, 211 patients with psoriasis (4 to 17 years of age) were initially randomly assigned to a double-blind trial of 12 once-weekly subcutaneous injections of placebo or 0.8 mg of etanercept per kilogram of body weight (to a maximum of 50 mg), followed by 24 weeks of once-weekly open-label etanercept. At week 36, 138 patients underwent a second randomization to placebo or etanercept to investigate the effects of withdrawal and retreatment. The primary end point was 75% or greater improvement from baseline in the psoriasis area-and-severity index (PASI 75) at week 12. Secondary end points included PASI 50, PASI 90, physician's global assessment of clear or almost clear of disease, and safety assessments.

Results: At week 12, 57% of patients receiving etanercept achieved PASI 75, as compared with 11% of those receiving placebo (P<0.001). A significantly higher proportion of patients in the etanercept group than in the placebo group had PASI 50 (75% vs. 23%), PASI 90 (27% vs. 7%), and a physician's global assessment of clear or almost clear (53% vs. 13%) at week 12 (P<0.001). At week 36, after 24 weeks of open-label etanercept, rates of PASI 75 were 68% and 65% for patients initially assigned to etanercept and placebo, respectively. During the withdrawal period from week 36 to week 48, response was lost by 29 of 69 patients (42%) assigned to placebo at the second randomiza-

tion. Four serious adverse events (including three infections) occurred in three patients during treatment with open-label etanercept; all resolved without sequelae.

Conclusions: Etanercept significantly reduced disease severity in children and adolescents with moderate-to-severe plaque psoriasis.

Teriparatide or Alendronate in Glucocorticoid - Induced Osteoporosis.

Saag KG, Shane E, Boonen S, Marín F, Donley DW, Taylor KA, Dalsky GP, Marcus R.
N Engl J Med 2007;357:2028-39

Η τεριπαρατίδη είναι αποτελεσματική σε σχέση με την αλενδρονάτη στην οστεοπόρωση από κορτικοστεροειδή

Background: Bisphosphonate therapy is the current standard of care for the prevention and treatment of glucocorticoid-induced osteoporosis. Studies of anabolic therapy in patients who are receiving long-term glucocorticoids and are at high risk for fracture are lacking.

Methods. In an 18-month randomized, double-blind, controlled trial, we compared teriparatide with alendronate in 428 women and men with osteoporosis (ages, 22 to 89 years) who had received glucocorticoids for at least 3 months (prednisone equivalent, 5 mg daily or more). A total of 214 patients received 20 μg of teriparatide once daily, and 214 received 10 mg of alendronate once daily. The primary outcome was the change in bone mineral density at the lumbar spine. Secondary outcomes included changes in bone mineral density at the total hip and in markers of bone turnover, the time to changes in bone mineral density, the incidence of fractures, and safety.

Results: At the last measurement, the mean (±SE) bone mineral density at the lumbar spine had increased more in the teriparatide group than in the alendronate group (7.2±0.7% vs. 3.4±0.7%, P<0.001). A significant difference between the groups was reached by 6 months (P<0.001). At 12 months, bone mineral density at the total hip had increased more in the teriparatide group. Fewer new vertebral fractures occurred in the teriparatide group than in the alendronate group (0.6% vs. 6.1%, P=0.004); the incidence of nonvertebral fractures was similar in the two groups (5.6% vs. 3.7%, P=0.36). Significantly more patients in the teriparatide group had at least one elevated measure of serum calcium.

Conclusions: Among patients with osteoporosis who were at high risk for fracture, bone mineral density increased more in patients receiving teriparatide than in those receiving alendronate.