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Intravenous application of omega-3 fatty acids in patients with active rheumatoid arthritis. The ORA-1 trial. An open pilot study.

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Abstract

The objective of this work was to assess the therapeutic efficacy and tolerability of intravenously applied n-3-PUFA in patients with active rheumatoid arthritis (RA). Thirty-four patients with active RA [identified as having a DAS28 (disease activity score including a 28 joint count) > 4.0] were enrolled into this 5-wk open pilot study (one group design). From the time of screening (visit 0, or V0), background therapy had to remain unchanged. Patients received 2 mL/kg (= 0.1-0.2 g fish oil/kg) fish oil emulsion intravenously on 7 consecutive days (Visit 1-Visit 2, or V1-V2) in addition to their background therapy. A decrease of the DAS28 > 0.6 at day 8 (Visit 2) was the primary efficacy measure. Moreover, the DAS28 at day 35 (Visit 3, or V3), the modified Health Assessment Questionnaire, the American College of Rheumatology (ACR) response criteria (V2, V3) and the Short Form-36 (V3) were assessed. Thirty-three patients completed the trial. The mean DAS28 at V1 was 5.45;at V2, 4.51 ($P < .001$ V1-V2) and at V3, 4.73 ($P < .001$ V1-V3; V2-V3, not significantly different). Of the 34 patients, 56% achieved a reduction of the DAS28 > 0.6 at V2 (mean 1.52); 27% > 1.2. At V3, 41% of the patients showed a DAS28 reduction > 0.6 (mean 1.06), and 36% > 1.2. ACR 20 and 50% responses at V2 were seen in 29 and 12% of patients, respectively; at V3, the comparable values were 18 and 9%, respectively. Overall tolerability was excellent. Intravenous application of n-3-PUFA (as an add-on therapy) was considerably well tolerated and led to improvement of the disease activity status in a reasonable number of RA patients. Future trials are warranted to answer whether the intravenous application of n-3-PUFA constitutes a therapeutic option in RA patients.

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