

Efficacy and safety of avocado/soybean unsaponifiables in the treatment of symptomatic osteoarthritis of the knee and hip. A prospective, multicenter, three-month, randomized, double-blind, placebo-controlled trial.

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One of the objectives of symptomatic slow-acting drugs for osteoarthritis is to reduce the need for drugs with a less favorable safety profile, mainly analgesics and nonsteroidal antiinflammatory drugs (NSAIDs). We conducted a three-month, prospective, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy of avocado/soybean unsaponifiables in terms of NSAID use reduction. Patients with primary femorotibial or hip osteoarthritis (OA) (ACR criteria and Kellgren-Lawrence radiological stage IB, II, or III) of at least six months' duration with regular pain for more than three months requiring therapy with NSAID (visual analog scale score \geq 25 mm and Lequesne's index on therapy \geq 4) were given one capsule per day of avocado/soybean unsaponifiables or a placebo for three months. During the first 45 days, patients in both groups were also given one of seven predefined NSAIDs. The primary efficacy criteria was the rate of patients taking back a NSAID and the delay before re-intake. Secondary efficacy criteria were the total dose of NSAID, overall ratings by the patient and by the physician, the visual analog scale pain score and the functional index. Of the 164 included patients, 163 were evaluable, 80 in the active drug group and 83 in the placebo group. Mean age was 62.9 \pm 8.8 years. The diagnosis was femorotibial OA in 101 patients and hip OA in 62. Data were collected on day 45 in 153 patients (77 on the active drug and 76 on the placebo). The number of patients who took back NSAID therapy was significantly smaller in the group treated by avocado/soybean unsaponifiables (33; 43.4%) than in the placebo group (53; 69.7%) ($P < 0.001$). Also, beyond day 54, the time spent off NSAID therapy was shorter in the placebo group. The functional index showed a significantly greater improvement in the active drug group (-2.3 \pm 2.6) than in the placebo group (-1.0 \pm 2.6) ($P < 0.01$). Pain scores over time were similar in the two groups. Overall patient ratings were significantly better in the active drug group ($P < 0.01$). Safety was oggd in both groups. After six weeks, avocado/soybean unsaponifiables reduced the need for NSAID in patients with lower limb OA.

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- Multicenter Study

- Randomized Controlled Trial

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