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Flavocoxid is as effective as naproxen for managing the signs and symptoms of osteoarthritis of the knee in humans: a short-term randomized, double-blind pilot study ☆, ☆☆

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Abstract

Flavocoxid (Limbrel), a proprietary mixture of flavonoid molecules (baicalin and catechin), was tested against a traditional nonsteroidal anti-inflammatory drug, naproxen, for the management of the signs and symptoms of moderate osteoarthritis (OA) in humans. Discomfort and global disease activity were used as the primary end points, and safety assessments were also taken for both treatments as a secondary endpoint. In this double-blind study, 103 subjects were randomly assigned to receive either flavocoxid [500 mg twice daily (BID)] or naproxen (500 mg BID) in a 1-month onset of action trial. Outcome measures included the short Western Ontario and McMaster University Osteoarthritis Index, subject Visual Analogue Scale for discomfort and global response, and investigator Visual Analogue Scale for global response and fecal occult blood. Both flavocoxid and naproxen showed significant reduction in the signs and symptoms of knee OA ($P \leq .001$). There were no statistically detectable differences between the flavocoxid and naproxen groups with respect to any of the outcome variables. Similarly, there were no statistically detectable differences between the groups with respect to the rate of improvement, although there was a trend toward a higher incidence of edema and nonspecific musculoskeletal discomfort in the naproxen group. In this short-term pilot study, flavocoxid was as effective as naproxen in controlling the signs and symptoms of OA of the knee and would present a safe and effective option for those individuals on traditional nonsteroidal anti-inflammatory drugs or cyclooxygenase-2 inhibitors. A low incidence of adverse events was reported for both groups.

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Abbreviations

AE, adverse event; BID, twice daily; COX, cyclooxygenase; K&L, Kellgren & Lawrence; LOX, lipoxygenase; NF-κB, nuclear factor κB; LTB_4, leukotriene B4; NSAID, nonsteroidal anti-inflammatory drugs; OA, osteoarthritis; PGAD, physician's global assessment of disease activity; PLA_2, phospholipase A2; SGAD, subject's global assessment of disease activity; SGADc, subject's global assessment of disease related discomfort; VAS, Visual Analogue Scale; WOMAC, Western Ontario and McMaster University Osteoarthritis Index

MeSH

Osteoarthritis [05.550.114.606]; Anti-Inflammatory Agents [D27.505.954.158]; Flavonoids [D03.438.150.266.450]

Keywords

Osteoarthritis; Flavocoxid; Limbrel; Flavonoid; Baicalin; Catechin; Medical food; Dual inhibition; Cyclooxygenase; Lipoxygenase; Randomized trial; Comparator; WOMAC; VAS; Nonsteroidal anti-inflammatory drugs; NSAID; Clinical trial

Cited by (44)

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2022, European Journal of Pharmacology

Citation Excerpt :

...Studies have compared Flavocoxid (Limbrel), a prescription medical food composed of a mixture of baicalin and catechin, to naproxen, a traditional NSAID. One study showed that both flavocoxid and naproxen reduce the symptoms of knee OA after one month of trial onset (Levy et al., 2009). In a post-marketing study, flavocoxid demonstrated good efficacy in OA management and reduced gastrointestinal adverse effects,...

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2021, Clinical Therapeutics

Citation Excerpt :

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2020, Osteoarthritis and Cartilage

Citation Excerpt :

...The efficacy of flavocoxid was based on two multicenter, randomized, double-blind controlled trials comparing flavocoxid 500 mg twice daily to prescription naproxen 500 mg. The first of these, was a 4-week blinded trial of 105 OA patients2. Clinical endpoints were measured via patient- and physician-reported outcomes and included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) as well as timed walk measures; results showed comparability between flavocoxid and naproxen....

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2016, Regulatory Toxicology and Pharmacology

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...For instance, UP446, a) neither inhibit nor potentiate bleeding time when combined with Aspirin in mice administered at a human equivalent daily dose of 569 mg (Pillai et al., 2010), b) produced no evidence of toxicity in ophthalmological, neurological, body weight, feed consumption, organ weight changes, gross finding, clinical or histopathological analysis administered daily to rats for 90 days at oral dosages of 250mg/kg-1000 mg/kg (Yimam et al., 2010; Burnett et al., 2007a), c) exhibited no mucosal or duodenal lesions administered orally to rats for over 9 weeks at a dose level equivalent to human 370 mg (Burnett et al., 2007a), and d) resulted in no toxicity in all in-life, clinical chemistry, hematology, and histopathology analyses administered orally to rats at a repeated daily dose levels of 500, 1000 and 2000 mg/kg/day for 26-weeks (Lee et al., 2013). Supplementing the preclinical safety findings, substantial reports have been documented in clinical studies attesting its beneficial use in the osteoarthritis management and relative tolerance in human (Arjmandi et al., 2014; Sampalis and Brownell, 2012; Levy et al., 2010a,b; Levy et al., 2009). Moreover, besides their rather tolerable characteristic during non-reproductive evaluations, extracts and active compounds from both S. baicalensis and A. catechu have been investigated in preclinical in vivo studies for their potential toxicity during the course of embryo-fetal development and determined relatively safe (Morita et al., 2009; Lesser et al., 2015; Tian et al., 2009....

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☆☆ Clinical Trial Registration number: ClinicalTrials.gov > NCT00303017 >.

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