Efficacy and tolerance of Harpagophytum procumbens versus diacerhein in treatment of osteoarthritis

A randomized, double-blind, multicenter trial in France finds that Devil's claw (Harpagophytum procumbens), a South African herb, may be as effective as the slow-acting drug, diacerhein, for the relief of osteoarthritis (OA) pain. For 4 months, 122 patients between the ages of 30 and 79 with OA of the knee or hip received either Harpadol (6 capsules/day, each containing 435 mg of Harpagophytum procumbens) or 100 mg/day of diacerhein. By the end of the trial, the two agents were found to reduce pain similarly, according to the visual analog scale of pain. On a scale of 0 to 100, pain in the Devil's claw group fell from 63.6 to 31.3 after 16 weeks, while pain in the diacerhein group fell from 61.6 to 35.8. In addition, patients in the Devil's claw group used fewer NSAIDs and analgesics and experienced significantly fewer side effects than those in the diacerhein group. Diarrhea was the most commonly reported side effect in both groups. Based on their findings, the researchers conclude that Harpadol "is an effective therapeutic agent in osteoarthritis and can be safely administered to patients."


Evaluation of acute and chronic treatments with Harpagophytum procumbens on Freund's adjuvant-induced arthritis in rats

The extract of Harpagophytum procumbens, widely utilized in Europe and, more recently, in other countries, is traditionally indicated to treat inflammatory processes. Harpagophytum procumbens acts by way of interleukins and leukocyte migration to the painful and inflamed joint area. Chemically, its secondary tuberous roots contain iridoid glycosides, harpagogide, procumbide, and harpagoside, as the active principle. The purpose of the present study was evaluate the therapeutic potential as anti-inflammatory and analgesic agent in rat model of Freund's adjuvant-induced arthritis both in the acute and chronic phases. The animals were injected with Freund's adjuvant in sub-plantar tissue of the right posterior paw and randomly assigned in acute (25, 50, or 100 mg/kg) or chronic (100 mg/kg) treatments with Harpagophytum procumbens solution test or vehicle. Then, submitted to behavioral test and assessment of body weight and right paw's measurements. The results show that Harpagophytum procumbens extract increased the animals 'latency of paws' withdrawal, indicating a protective effect against the pain induced by the thermal stimulus, both in acute and chronic treatments. In addition to reduction in the right paw edema in the experimental groups when compared to control group. Thus, the data showed anti-inflammatory and peripheral analgesic properties of Harpagophytum procumbens extract with all doses tested, thus confirming its indication for inflammatory processes. Andersen ML, Santos EH, Seabra Mde L, da Silva AA, Tufik S. J Ethnopharmacol. 2004 Apr;91(2-3):325-30.

Treatment of patients with arthrosis of hip or knee with an aqueous extract of devil's claw (Harpagophytum procumbens DC.)

Preparations made from the secondary tubers of Devil's claw (Harpagophytum procumbens) are successfully used in patients with rheumatic diseases (arthrosis and low back pain). In order to add data on the efficacy and long-term safety of an aqueous extract (Doloteffin; 2400 mg extract daily, corresponding to 50 mg harpagoside), which has been tested successfully in patients with low back pain, an uncontrolled multicentre drug surveillance study for about 12 weeks was conducted in 75 patients with arthrosis of the hip or knee. To standardize the assessment of treatment effects, the Western Ontario and McMaster Universities (WOMAC) osteoarthritis index (10 point scale) as well as the 10 cm VAS pain scale were used. The results of the study revealed a strong reduction of pain and the symptoms of osteoarthritis. There was a relevant improvement of each WOMAC subscale as well as of the total WOMAC index: 23.8% for the pain subscale, 22.2% for the stiffness subscale and 23.1% for the physical function subscale. The WOMAC total score was reduced by 22.9%. VAS pain scores were decreased by 25.8% for actual pain, 25.2% for average pain, 22.6% for worst pain and 24.5% for the total pain score. The physicians reported a continuous improvement in typical clinical findings such as 45.5% for pain on palpation, 35% for limitation of mobility and 25.4% for joint crepitus. Only two cases of possible adverse drug reactions were reported (dyspeptic complaints and a sensation of fullness). Although this was an
A randomized double-blind pilot study comparing Doloteffin and Vioxx in the treatment of low back pain

OBJECTIVE: This randomized, double-dummy, double-blind pilot study of acutely exacerbated low back pain was aimed to inform a definitive comparison between Doloteffin, a proprietary extract of Harpagophytum, and rofecoxib, a selective inhibitor of cyclo-oxygenase-2 (COX-2). METHODS: Forty-four patients (phyto-anti-inflammatory drug-PAID-group) received a daily dose of Doloteffin containing, inter alia, 60 mg of harpagoside for 6 weeks and 44 (non-steroidal anti-inflammatory drug-NSAID-group) received 12.5 mg/day of rofecoxib. All were allowed rescue medication of up to 400 mg/day of tramadol. Several outcome measures were examined at various intervals to obtain estimates of effect size and variability that might be used to decide the most suitable principal outcome measure and corresponding numbers required for a definitive study. RESULTS: Forty-three PAID and 36 NSAID patients completed the study. Ten PAID and 5 NSAID patients reported no pain without rescue medication for at least 5 days of the 6th week of treatment. Eighteen PAID and 12 NSAID patients had more than a 50% reduction in the week's average of their pain scores between the 1st and 6th weeks. The mean percentage decrease from baseline in the pain component of the Arhus Index was 23 (S.D. 52) in PAID and 26 (S.D. 43) in NSAID. The corresponding measures for the overall Arhus Index were 11 (31) and 16 (24) and, for the Health Assessment Questionnaire, 7 (8) and 6 (7). Tramadol was used by 21 PAID patients and 13 NSAID patients. Fourteen patients in each group experienced 39 adverse effects, of which 28 (13 in PAID) were judged to some degree attributable to the study medications. CONCLUSION: Though no significant intergroup differences were demonstrable, large numbers will be needed to show equivalence. Chrubasik S, Model A, Black A, Pollak S. Rheumatology (Oxford). 2003 Jan;42(1):141-8.

Comparison of outcome measures during treatment with the proprietary Harpagophytum extract doloteffin in patients with pain in the lower back, knee or hip

Besides checking estimates of effectiveness and safety of using the proprietary Harpagophytum extract Doloteffin, this postmarketing surveillance compared various disease-specific* and generic** measures of effect. We enrolled 250 patients suffering from nonspecific low back pain (Back group: n = 104) or osteoarthritic pain in the knee (Knee group: n = 85) or hip (Hip group: n = 61). They took an 8-week course of Doloteffin at a dose providing 60 mg harpagoside per day. The measures of effect on pain and disability included the percentage changes from baseline of established instruments (Arhus low back pain index*, WOMAC index*, German version of the HAQ**) and unvalidated measures (total pain index*, three score index*, the patient’s global assessment** of the effectiveness of treatment). Patients also received a diary for the daily recording of their pain and any additional treatments for it. The three groups differed in age, weight and characteristics of initial pain. 227 patients completed the study. Multivariate analysis confirmed that several dimensions of effect were recorded by the several outcome measures but, in all groups, both the generic and disease-specific outcome measures improved by week 4 and further by 8. In multivariable analysis, the improvement tended to be more when the initial pain and disability score was more: older patients tended to improve less than younger, the hip group tended to improve convincingly more than the back group, whereas the improvement in the knee group was less readily differentiated from that in the back group. The subgroup of Back patients who required NSAIDs during the 8 weeks used significantly more per patient than patients in the other two groups, but that requirement also declined more with time. About 10% of the patients suffered from minor adverse events that could possibly have been attributable to Doloteffin. Between 50% and 70% of the patients benefitted from Doloteffin with few adverse effects. Thus, Doloteffin is well worth considering for osteoarthritic knee and hip pain and nonspecific low back pain. Chrubasik S, Thanner J, Kunzel O, Conradt C, Black A, Pollak S. Phytomedicine. 2002 Apr;9(3):181-94.
[Effects of Harpagophytum procumbens LI 174 (devil's claw) on sensory, motor und vascular muscle reagibility in the treatment of unspecific back pain] [Article in German]

PROBLEM: This randomised, double-blind, placebo controlled study was intended to investigate the effects of Harpagophytum procumbens (Devil's Claw) on sensory, motor and vascular mechanisms of muscle pain. In addition to clinical efficacy and tolerability, possible action mechanisms were analysed by means of experimental algesimetric methods. METHODOLOGY: The study was performed on patients with slight to moderate muscular tension or slight muscular pain of the back, shoulder and neck. On a double-blind randomised basis the verum group received 2x1 film tablets per day, i.e. 2x480 mg/day, of Harpagophytum extract LI 174 (Rivoltan(R)) at 8.00 a.m. and 8.00 p.m. over a certain period. The duration of the therapy was 4 weeks. Data recording at 14-day intervals was made using a visual analogue scale, pressure algometer test, recording of antinociceptive muscular reflexes, muscle stiffness test, EMG surface activity, muscular ischaemia test, clinical global score and subjective patient and physician ratings. RESULTS: A total of 31 patients in the verum group and 32 in the placebo group were treated. After four weeks of treatment there was found to be a clear clinical efficacy of the verum on the clinical global score and in the patient and physician ratings. Highly significant effects were found in the visual analogue scale, the pressure algometer test, the muscle stiffness test and the muscular ischaemia test. No difference from placebo was found in the recording of antinociceptive muscular reflexes or in the EMG surface activity. Tolerability was good; no serious adverse effects occurred. CONCLUSIONS: A highly significant clinical efficacy was achieved with a monotherapy of Harpagophytum dry extract LI 174 after four weeks' treatment at a dosage of 2x480 mg/day in cases of slight to moderate muscular pain. With regard to the action mechanisms investigated, it may be concluded that treatment with Harpagophytum extract LI 174 may be expected to have a significant influence on sensory and vascular muscular response and bring about a reduction in muscle stiffness. No central nervous effects were discovered. Gobel H, Heinze A, Ingwersen M, Niederberger U, Gerber D. Schmerz. 2001 Feb;15(1):10-8.

Efficacy and tolerance of Harpagophytum extract LI 174 in patients with chronic non-radicular back pain

The aim of this open, multicentre study was to evaluate the clinical effectiveness and tolerance of the Devil's Claw extract LI 174 in patients suffering from non-radicular back pain over a period of at least 6 months. A total of 130 patients were treated twice a day with tablets containing 480 mg LI 174. The treatment lasted for 8 weeks. The effectiveness was judged according to the Multidimensional Pain Scale (MPS), Arhus back pain index and to parameters evaluating the mobility of the lumbar spine (finger-floor distance, Schober's sign). Data from 117 patients were evaluated for efficacy. The results showed a significant improvement of pain symptoms and mobility of the affected sections of the patient's spine in the course of treatment. No serious side effects were observed. In view of the excellent compliance and tolerability the investigated extract appears to be an effective plant alternative for the treatment of chronic back pain. However, further studies will be needed to clarify the therapeutic value of this plant remedy. Laudahn D, Walper A. Phytother Res. 2001 Nov;15(7):621-4.

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