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## Oral herbal therapies for treating osteoarthritis.

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## **Abstract**

**BACKGROUND:** Medicinal plant products are used orally for treating **osteoarthritis**. Although their mechanisms of action have not yet been elucidated in full detail, interactions with common inflammatory mediators provide a rationale for using them to treat osteoarthritic complaints.

**OBJECTIVES:** To update a previous Cochrane review to assess the benefits and harms of oral medicinal plant products in treating osteoarthritis.

**SEARCH METHODS:** We searched electronic databases (CENTRAL, MEDLINE, EMBASE, AMED, CINAHL, ISI Web of Science, World Health Organization Clinical Trials Registry Platform) to 29 August 2013, unrestricted by language, and the reference lists from retrieved trials.

**SELECTION CRITERIA:** Randomised controlled trials of orally consumed herbal interventions compared with placebo or active controls in people with **osteoarthritis** were included. Herbal interventions included any plant preparation but excluded homeopathy or aromatherapy products, or any preparation of synthetic origin.

**DATA COLLECTION AND ANALYSIS:** Two authors used standard methods for trial selection and data extraction, and assessed the quality of the body of evidence using the GRADE approach for major outcomes (pain, function, radiographic joint changes, quality of life, withdrawals due to adverse events, total adverse events, and serious adverse events).

MAIN RESULTS: Forty-nine randomised controlled studies (33 interventions, 5980 participants) were included. Seventeen studies of confirmatory design (sample and effect sizes pre-specified) were mostly at moderate risk of bias. The remaining 32 studies of exploratory design were at higher risk of bias. Due to differing interventions, meta-analyses were restricted to Boswellia serrata (monoherbal) and avocado-soyabean unsaponifiables (ASU) (two herb combination) products. Five studies of three different extracts from Boswellia serrata were included. High-quality evidence from two studies (85 participants) indicated that 90 days treatment with 100 mg of enriched Boswellia serrata extract improved symptoms compared to placebo. Mean pain was 40 points on a 0 to 100 point VAS scale (0 is no pain) with placebo, enriched Boswellia serrata reduced pain by a mean of 17 points (95% confidence interval (CI) 8 to 26); number needed to treat for an additional beneficial outcome (NNTB) 2; the 95% CIs did not exclude a clinically significant reduction of 15 points in pain. Physical function was 33 points on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) 0 to 100 point subscale (0 is no loss of function) with placebo, enriched Boswellia serrata improved function by 8 points (95% CI 2 to 14); NNTB 4. Assuming a minimal clinically important difference of 10 points, we cannot exclude a clinically important benefit in some people. Moderatequality evidence (one study, 96 participants) indicated that adverse events were probably reduced with enriched Boswellia serrata (18/48 events versus 30/48 events with placebo; relative risk (RR) 0.60, 95% CI 0.39 to 0.92). Possible benefits of other Boswellia serrata extracts over placebo were confirmed in moderatequality evidence from two studies (97 participants) of Boswellia serrata (enriched) 100 mg plus non-volatile oil,

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and low-quality evidence from small single studies of a 999 mg daily dose of Boswellia serrata extract and 250 mg daily dose of enrichedBoswellia serrata. It was uncertain if a 99 mg daily dose of Boswellia serrata offered benefits over valdecoxib due to the very low-quality evidence from a small single study. It was uncertain if there was an increased risk of adverse events or withdrawals with Boswellia serrata extract due to variable reporting of results across studies. The studies reported no serious adverse events. Quality of life and radiographic joint changes were not measured. Six studies examined the ASU product Piasclidine®. Moderate-quality evidence from four studies (651 participants) indicated that ASU 300 mg produced a small and clinically questionable improvement in symptoms, and probably no increased adverse events compared to placebo after three to 12 months treatment. Mean pain with placebo was 40.5 points on a VAS 0 to 100 scale (0 is no pain), ASU 300 mg reduced pain by a mean of 8.5 points (95% CI 1 to 16 points); NNTB 8. ASU 300 mg improved function (standardised mean difference (SMD) -0.42, 95% CI -0.73 to -0.11). Function was estimated as 47 mm (0 to 100 mm scale, where 0 is no loss of function) with placebo, ASU 300 mg improved function by a mean of 7 mm (95% CI 2 to 12 mm); NNTB 5 (3 to 19). There were no differences in adverse events (5 studies, 1050 participants) between ASU (53%) and placebo (51%) (RR 1.04, 95% CI 0.97 to 1.12); withdrawals due to adverse events (1 study, 398 participants) between ASU (17%) and placebo (15%) (RR 1.14, 95% CI 0.73 to 1.80); or serious adverse events (1 study, 398 participants) between ASU (40%) and placebo (33%) (RR 1.22, 95% CI 0.94 to 1.59). Radiographic joint changes, measured as change in joint space width (JSW) in two studies (453 participants) did not differ between ASU 300 mg treatment (-0.53 mm) and placebo (-0.65 mm); mean difference of -0.12 (95% CI -0.43 to 0.19). Moderate-quality evidence from a single study (156 participants) confirmed possible benefits of ASU 600 mg over placebo, with no increased adverse events. Low-quality evidence (1 study, 357 participants) indicated there may be no differences in symptoms or adverse events between ASU 300 mg and chondroitin sulphate. Quality of life was not measured. All other herbal interventions were investigated in single studies, limiting conclusions. No serious side effects related to any plant product were reported.

**AUTHORS' CONCLUSIONS:** Evidence for the proprietary ASU product Piasclidine® in the treatment of **osteoarthritis** symptoms seems moderate to high for short term use, but studies over a longer term and against an apparently active control are less convincing. Several other medicinal plant products, including extracts of Boswellia serrata, show trends of benefits that warrant further investigation in light of the fact that the risk of adverse events appear low. There is no evidence that Piasclidine® significantly improves joint structure, and limited evidence that it prevents joint space narrowing. Structural changes were not tested for with any other herbal intervention. Further investigations are required to determine optimum daily doses producing clinical benefits without adverse events.

## **Update of**

Herbal therapy for treating osteoarthritis. [Cochrane Database Syst Rev. 2001]

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