

Complex ayurvedic treatment for osteoarthritis of the knee (CARAKA) - a randomized controlled trial

Summary:

Background

Traditional Indian Medicine Ayurveda uses complex treatment approaches. Treatment is based on Ayurvedic diagnosis and includes manual therapies, lifestyle and nutritional advice, dietary supplements, medication, yoga and purification techniques. In India, Ayurveda strategies are often used for the treatment of osteoarthritis of the knee (OA knee), however, no systematic data is available on their effectiveness in comparison to standard care.

Objective:

The aim is to evaluate the effectiveness of complex Ayurvedic treatment in comparison to conventional standard care for treating OA symptoms in patients with OA knee.

Methods and Design:

150 patients will be included in a prospective, multicenter, randomized, controlled trial. Patients between 40 and 70 years, diagnosed with OA knee, following ACR criteria and an average pain intensity of ≥ 40 mm on a 100 mm VAS in the affected knee at baseline will be randomized into two groups. In the Ayurveda group treatment will include tailored combinations of manual treatments, massages, dietary and lifestyle advice, consideration of selected foods, nutritional supplements, yoga posture advice and knee massage. Patients in the conventional group will receive self-care advice, pain medication, weight-loss-advice (if overweight) and physiotherapy following current international guidelines. Both groups receive 15 treatment sessions during 12 weeks. The overall individual study period is 12 months. Outcomes will be evaluated after 6 and 12 weeks and 6 and 12 month. The primary endpoint is the change in the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) after 12 weeks. Secondary outcomes are WOMAC subscales, Pain Disability Index, VAS for pain and sleep quality, Pain Experience Scales, Quality of Life (SF-36), Profile of Mood States, Likert Scales for patient satisfaction, patient diaries and safety.

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