Objective: To assess both the short-term and the long-term effectiveness of spa therapy in patients with primary knee osteoarthritis (OA) in a prospective, randomized, single blind, controlled trial.

Materials and Methods: 103 outpatients with OA of the knee according to the ACR criteria (1) were enrolled. Patients were randomized 1:1 and allocated into two groups: 53 patients (Group A) received in addition to usual treatment (exercise, NSAIDs and/or analgesics, established SYSADOAs) a combination of daily local mud-packs applied on both knees for 20 min at an initial temperature of 45°Cand bicarbonate–sulphate-calcic mineral bath water at 38°C for 15 min, from the spa centre of Chianciano Terme (Siena, Italy) for 12 applications carried out over a period of 2 weeks. 50 patients (Group B, controls) continued routine ambulatory care. Clinical assessments were performed at basal time after 2 weeks, after 3, 6, 9 and 12 months – end of the study. The primary outcome criteria were the change from baseline to month 12 in WOMAC - Total Pain Score (W-TPS) (range 0-20)* and in WOMAC – Total Physical Function Score (W-TPFS) (range 0-68)* scored by a 5-point Likert scale. A set of secondary outcomes was also assessed such as WOMAC Total Stiffness Score (W-TSS), Physical Component Summary (PCS) and Mental Component Summary (MCS) of SF-12 (ranges 0-100) and consumption of analgesic medications (paracetamol and/or NSAIDs).

Results: Ten patients (9.5%) withdrew from the study: 2 in the spa-group and 8 (16%) in the control group. The assessment of pain showed a very significant improvement (p<0.001) in patients treated with mud-packs until 6 months and a less significant reduction (p<0.05) after 9 and 12 months. The control group showed a significant improvement after 2 weeks and 3 months, however this improvement is less expressed than in group A.

The differences between the two groups were significant already from 2 weeks and lasted during the follow-up.

A similar trend was observed for the WOMAC - Physical Function in the group A, group B showed a significant worsening after 6 months persisting throughout the follow-up.

The results obtained from the quality of life, SF-12 survey showed a significant improvement (p<0.001) in Physical Component, persisting throughout the follow-up period in group A. No significant modifications were found in group B during the study period.

On the contrary, significant improvement of the Mental Component Summary of SF-12 was
shown at the end of the therapy in group A, but no significant differences were observed in the other time of the follow-up.

These effect on pain and function were also confirmed by the observed reduction of symptomatic drugs consumption. Tolerability of spa therapy seemed to be good, with light and transitory side effects.

**Conclusions:** In conclusion our results, in keeping with other studies (2, 3) confirm that the beneficial effects of mud-bath therapy in patients with knee OA last over time, with significant reduction on the painful symptomatology and a significant improvement on functional capacities and on quality of life. Spa therapy can represent a useful backup to pharmacological treatment of knee OA or a valid alternative for patients who do not tolerate pharmacological treatments.

**Keywords:** Knee Osteoarthritis, Mud-Bath Therapy, Bicarbonate–Sulphate-Calcic mineral water

**References**