

# Lombatherm study news of an international randomized trial on low back pain

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## Background and rationale

Chronic low back pain is a public health issue as much by the repercussions it has on the functional capacities of patients as by its economic and social cost.

A number of recommendations of good clinical practice had proposed the spa treatment in low back pain, mainly on the basis of studies carried out by the University of Nancy in the 90s. Despite their qualities, these ancient works have certain methodological limitations: absence of main criterion, analysis in intention to treat. On the other hand, they used an immediate cure-deferred cure design that could overestimate the effect of the spa treatment. On the other hand, there is little or no study of the older populations that are usually frequented by spas.

## Primary and secondary objectives

*Primary objective:* Evaluation of the therapeutic effect of the thermal treatment in addition to the usual care in chronic low back pain versus usual care

*Secondary objectives:* Evaluation of the therapeutic effect of the thermal treatment, in each of the thermal centers. Evaluation of the side effects of the thermal treatment. Evaluation of the benefit / risk ratio, cost / effectiveness, cost / utility of thermal treatment in chronic low back pain.

## Methods

Methods (study design, population, inclusion criteria, non-inclusion, main and secondary evaluation criteria, number of topics to be included, statistical analysis...)

*Design of the study:* Multicenter randomized trial. Preference randomization will be replaced by the Zelen method because education was judged difficult to achieve in an international project and placebo intervention are not appropriate in preference trial (too much heterogeneity). Stratification is still by center and by the presence of a professional activity.

*Population concerned.* Adult patients with painful low back pain for at least three months.

*Investigation method.* Randomized controlled study in two parallel arms.

*Judgment criteria.*

Primary judgment criterion: Number of patients with clinically relevant improvement at 6 months of pain. Relevant improvement will be more than 30% on the pain VAS between the 1st examination and 6 months.

Secondary criteria: Variation of lumbar mobility: Schöber index, distance hand ground; Functional Test: Sit-Stand Test (Five-Times-Sit-to-Stand Test); Patient acceptable symptom state; Opinion of the patient and the physician on the improvement; Variations of the Assessment Scale of Functional Inability in Low Back Pain (EIFEL, French version of Rolland and Morris's questionnaire) instead of OSWESTRY that was not enough sensitive to change in a preliminary open study.

Variations of the EQ5D Quality of Life Questionnaires; Variations of associated treatments; Side effects: We removed the fear and avoidance belief (FABQ) questionnaire because it was not improved in our preliminary study.

*Number of topics to include.*

356 patients. There will be 5 visits (inclusion, Day 0, 1 month, 6 months and 1 year).

Intervention: Both groups will benefit from an information session on back pain and will be given a series of exercises to perform at home on back pain. At the end of the session, they will be given a booklet on back pain: French translation of the Back Book. The thermal group will receive a standardized thermal intervention decided by consensus between the spa practitioners. It will be issued over 18 days and 3 weeks with an interruption on Sunday. It will necessarily include underwater massages, supervised pool exercises and mud applications. Other care will be left to the discretion of the doctors at each station.

The same mandatory care will be carried out in the European centers.

**Expected results and prospects**

Pain is expected to improve at 6 months