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Methods

Prospective, multicentre, 3-arm, randomized controlled trial.

Main inclusion criteria: female, aged 30-65, suffering from FM according to ACR, with a Fibromyalgia Index Questionnaire (FIQ) score >40. Main exclusion criteria: male, pregnant or breast feeding women, change of the pharmacological treatment over the last 2 months, other active rheumatic or neurological disease.

Pre-existing background: analgesics, anxiolytics, hypnotics, antidepressants, anticonvulsants were continued at unchanged doses during the 6 months duration of the study.

Background

Current therapeutic modalities for fibromyalgia syndrome (FMS) do not provide satisfactory results to a high percentage of patients and new approaches have to be explored.

Objectives

To assess both safety and efficacy of a phytotherapy medication, Fib-19-01 compared to a food supplement with claimed analgesic properties (FSAP) and to the usual care alone, in female patients suffering from FMS.

Patients and methods

Treatments under study:

- **Fib-19-01:** 1 capsule “morning” at breakfast (constituted of acoman, ginger root, meadowsweet and royal jelly) and 1 capsule “evening” at dinner (passionflower, rhodiola, meadowsweet, quack grass and l-tyrosine).

- **FSAP:** Compositional matrix: constituted of magnesium, valerian, echinacea, garlic, willow and royal jelly. 1 capsule “morning” at breakfast and 1 capsule “evening” at dinner. FSAP was indistinguishable from Fib-19-01 to ensure the double-blinding.

- **No supplementary treatment (NoST):**

Visits: screening (i.e. 1 to 7 days before inclusion visit), inclusion (DG), follow-up visits at week 8, 16 and 24.

Efficacy outcomes:

- **Primary criterion:** improvement of the quality of life assessed by the change in the FIQ score between D0 and W24.

- **Secondary criterion:** variation of FIQ over time in repeated measurements, variation between D0 and W24 of the Fatigue Pichot scale, the Pittsburgh Sleep Quality Index (PSQI), the SF-12 Physical and Mental Health Summary Scales, the HAD scales for depression and anxiety.

Populations:

ITT and PP populations included 101 and 75 patients respectively. They were not statistically different and were in accordance with that expected: mean age 49, BMI 25, high percentage of antidepressant (75/101) and anticonvulsivant (28/101) treatments. At inclusion the 3 groups CAF-19-01, FSAP et NoST were not statistically different.

Results

The FIQ decrease throughout the follow-up was significant only in the Fib-19-01 group (p < 0.001). In intergroup comparison, there was a trend for an higher improvement for Fib-19-01 (-13.5) than in the 2 other groups (-5.4 and -5.6) (p = 0.08).

Analysis of variance in repeated measurements of FIQ showed a significant difference between Fib-19-01 and FSAP (p = 0.03).

No significant difference was found between FSAP and NoST groups.

All treatments were well and similarly tolerated.

Conclusion

A 6-month treatment with Fib-19-01 improved all MS scores excepted the physical SF 12, as opposed to FSAP and conventional treatment alone, which did not significantly improve any.

This study showed that Fibromyalgine® has a therapeutic effect in the FMS mainly on “fatigue” and on the components “emotion and social life” and “depression” of the disease, without safety concern.