MULTICENTER, PROSPECTIVE, CONTROLLED DOUBLE-BLIND STUDY COMPARING FIB-19-01 (FIBROMYALGINE®), A PHYTOTHERAPY TREATMENT FOR FIBROMYALGIA, TO A DIETARY SUPPLEMENT AND TO CONVENTIONAL TREATMENT IN PATIENTS SUFFERING FROM FIBROMYALGIA.

P. BERTIN[1], D. BARON[2], M. BARMAKI[3], I. RUSS[4], C. MAINDET-DOMINICI[5], P. FARDELLONE[6], P. GINIES[7], T. CONROZIER[8], J. NIZARD[9]

[1]Rheumatology, CHU Limoges, Limoges, [2]Rheumatology, CH Lannion, Lannion, [3]Pain, Clinique Mutualiste Eugène André, Lyon, [4]Pain, Hôpital résidence du Parc, Marseille, [5]Pain, CHU Grenoble, Grenoble, [6]Rheumatology, CHU Amiens, Amiens, [7]Pain, CHU Montpellier, Montpellier, [8]Rheumatology, Hôpital Nord Franche-Comté, Belfort, [9]Pain, CHU de Nantes, Nantes, France

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.

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.

Patients and methods

Treatments under study:

✓**Fib-19-01:** 1 capsule "morning" at breakfast (*constituted of acerola, ginger extracts, meadowsweet and royal jelly*) and 1 capsule "evening" at dinner (*passionflower, chamomile, meadowsweet, quack grass and L-Tyrosine*).

✓**FSAP**:(*Comparator mainly constituted of magnesium, valerian, escholtzia, ginseng, willow and sage*) 1 capsule "morning" at breakfast and 1 capsule "evening" at dinner. FSAP was undistinguishable from Fib-19-01 to ensure the double-blinding. Patient and evaluator, blinded to treatment group for Fib-19-01 and FSAP.

✓**No supplementary treatment (NoST)**

Visits: screening (i.e. 1 to 7 days before inclusion visit), inclusion (D0), follow-up visits at week 8, 16 and 24.

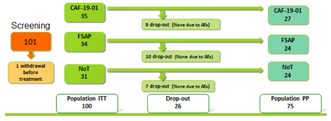
Efficacy outcomes:

✓**Primery criterion**: improvement of the quality of life assessed by the change in the FIQ score between D0 and W24

✓**Secondary criteria**: variation of FIQ over time in repeat 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:

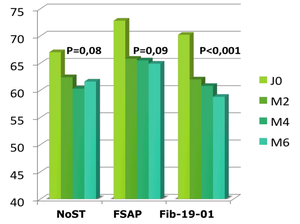
ITT and PP populations included 101 and 75 patients respectively. They were not statistically different and were in accordance with that expected: mean age 49, BMI 25, high percentage of antidepressant (75/101) and anticonvulsivant (28/101) treatments. At inclusion the 3 groups CAF-19-01, FSAP et NoST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



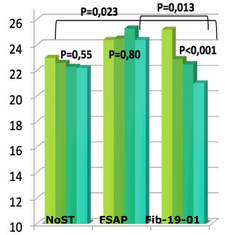
Results

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).



Results



On secondary criteria, **Fib-19-01 was superior to FSAP and NoST for:**

- **Pichot scale** (p = 0.013),
- **Mental and social SF12** (p = 0.018),
- **HAD depression** (p = 0.013).

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 FMS 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.

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