

[Abstract](#) ▾[Clin Rheumatol.](#) 2000;19(1):9-13.

## The effect of melatonin in patients with fibromyalgia: a pilot study.

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#### Abstract

The aim of the study was to determine the possible effect of melatonin treatment on disturbed sleep, fatigue and pain symptoms observed in fibromyalgia (FM) patients. Twenty-one consecutive patients with FM were included in an open 4-week-duration pilot study. Before and after treatment with melatonin 3 mg at bedtime, patients were evaluated using tender point count by palpation of 18 classic anatomical regions, pain score in four predesignated areas, pain severity on a 10 cm visual analogue scale (VAS), sleep disturbances, fatigue, depression, anxiety, and patient and physician global assessments, also by a VAS. Urine 6-sulphatoxymelatonin levels (aMT-6S) were measured in the patients and 20 age- and sex-matched controls. Nineteen patients completed the study. One patient withdrew because of migraine and another was lost to follow-up. At day 30, median values for the tender point count and severity of pain at selected points, patient and physician global assessments and VAS for sleep significantly improved with melatonin treatment. Other variables improved but did not reach statistical significance. Adverse events were mild and transient. Lower levels of aMT-6S were found in FM patients compared with normal median controls (+/-SD, 9.16 +/- 7.9 microg/24 h vs 16.8 +/- 12.8 microg/24 h) (p = 0.06). Although this is an open study, our preliminary results suggest that melatonin can be an alternative and safe treatment for patients with FM. Double-blind placebo controlled studies are needed.

PMID: 10752492 [PubMed - indexed for MEDLINE]



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