

primary studies - published RCT

## **Melatonin improves sleep and reduces nitrite in the exhaled breath condensate in cystic fibrosis--a randomized, double-blind placebo-controlled study.**

**Code:** PM20025642

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### **Study design (if review, criteria of inclusion for studies)**

randomized double-blind, placebo-controlled study

### **Participants**

20 patients with CF. One individual failed to conclude the study. All subjects were clinically stable when studied and without recent infectious exacerbation or hospitalization in the last 30 days.

### **Interventions**

Groups were randomized for placebo (n = 10; mean age 12.1 +/- 6.0) or 3 mg melatonin (n = 9; mean age 16.6 +/- 8.26) for 21 days.

### **Outcome measures**

Actigraphy was performed for 6 days before the start of medication and in the third week (days 14-20) of treatment. Isoprostane and nitrite levels were determined in exhaled breath condensate (EBC) at baseline (day 0) and after treatment (day 21).

### **Main results**

Melatonin improved sleep efficiency (P = 0.01) and tended to improve sleep latency (P = 0.08). Melatonin reduced EBC nitrite (P = 0.01) but not isoprostane. In summary, melatonin administration reduces nitrite levels in EBC and improves sleep measures in clinically stable CF patients.

### **Authors' conclusions**

The failure of melatonin to reduce isoprostane levels may have been a result of the low dose of melatonin used as a treatment.

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### **See also**

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### **Keywords**

Adolescent; Adult; Child; Hormones; Melatonin; Mental Disease-Psychiatric Conditions; Nitrites; pharmacological\_intervention; placebo; Sleep Disorders;