

# Adjuvant use of melatonin for pain management in endometriosis-associated pelvic pain

– a randomized double-blinded, placebo-controlled trial

L Söderman, Y Böttiger, M Edlund, H Järnbert-Pettersson, L Marions

## Conclusion

This randomized, double-blinded, placebo-controlled trial could not show that 20 mg of melatonin given orally at bedtime had better analgesic effect on EAPP as compared with placebo.

## Implications for future

We chose a higher dose than previously tested, for EAPP, with no adverse effect. The mean level of pain was perhaps too low in our study population to show any significant reduction. Since no adverse effect was noted, a future RCT in a larger population and with higher dose seems feasible.



## Background

Melatonin has analgetic and anti-oxidative properties, and very few side effects. Animal studies have shown reduction in size of endometrial lesions after melatonin therapy.

A human study has shown that 10 mg melatonin reduced endometriosis-associated pain (EAPP) compared with placebo .

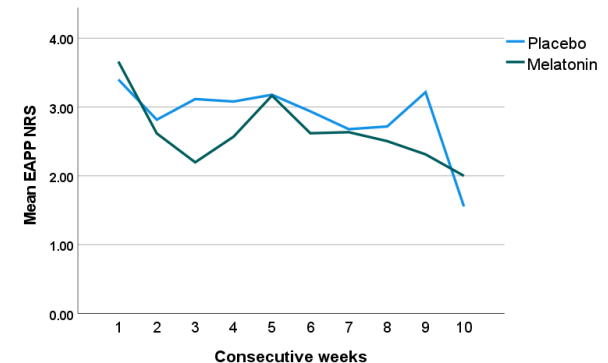
The effect on pain and inflammation seem to be dose-dependent.

## Method

We randomized 20 participants to melatonin and 20 to placebo. The study drug was ingested once daily at bedtime for two menstrual cycles/months.

The participants answered daily on questionnaires evaluating EAPP, dysuria, dyschezia, dyspareunia on a numeric rating scale and amount of analgesics in mg. Sleep, pain catastrophization and quality of life were also assessed.

*Ref Schwertner A, et al. Efficacy of melatonin in the treatment of endometriosis: a phase II, randomized, double-blind, placebo-controlled trial. Pain. 2013;154(6):874-881.*



Mean endometriosis-associated pain on a numeric rating scale was 3.3 units lower in the melatonin group ( $p=0.515$ ).

## Results

No clinically significant differences were seen between the groups in any of the outcomes. The melatonin group had 0.3 units lower mean of NRS than the placebo group ( $p=0.52$ , 95%CI -0.7 -1.4). Our pre-defined effect was 1.3 units, its inclusion in the confidence interval suggests the study could be underpowered, and inconclusive.

A "good experience" with the study drug was reported by 61% in the melatonin group and by 54% in the placebo group.