# Adjuvant use of melatonin for pain management in endometriosis-associated pelvic pain - a randomized double-blinded, placebo-controlled trial

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# Associated documentation

Variabellista.xlsx (14.16 KB)

# Citation

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# Creator/Principal investigator(s)

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# **Research principal**

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# Description

Purpose: Considering the pharmacological treatment options for endometriosis-associated pain are confined to hormonal therapy and analgesics, we studied the analgesic effect of 20 mg melatonin as an adjuvant therapy in women with endometriosis-associated pain.

Methods: This randomized double-blinded, placebo-controlled trial was conducted at the Research Center for Womens' Health at Södersjukhuset, a university hospital in Stockholm, Sweden. Forty women from 18 to 50 years of age with endometriosis and severe dysmenorrhea with or without chronic pelvic pain were given 20 mg Melatonin or placebo orally daily for two consecutive menstrual cycles or months. The level of pain was recorded daily via questionnaire on the 11-point numeric rating scale. A difference of 1.3 units was considered clinically significant. Clincaltrials.gov nr NCT03782740.

Results: Sixteen participants completed the study in the placebo group and 18 in the melatonin group. The difference in endometriosis-associated pain between the groups showed to be non-

significant statistically as well as clinically.

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 endometriosis-associated pain as compared with placebo. However, no adverse effects were observed.

The dataset consists of a csv fil (RCT\_mel\_endo.csv) with responses from the survey.

## Data contains personal data

Yes

Sensitive personal data

Yes

Type of personal data

#### pseudonymised

#### Code key exists

Yes

#### Language

Swedish

**Population** Fyrtio kvinnor, 18-50 år med endometrios och svår mensvärk

Study design Double-blind randomised trial

#### Number of individuals/objects

40

#### Data format / data structure

**Numeric** 

#### **Data collection 1**

- Mode of collection: Self-administered questionnaire
- Time period(s) for data collection: 2019-08-21 2021-06-27
- Instrument: RedCap (Technical instrument(s))
- Sample size: 40

## **Geographic spread**

Geographic location: Sweden

#### **Responsible department/unit**

Ki SÖS

## Contributor(s)

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#### **Ethics Review**

Stockholm - Ref. 2017/1177-21/2

#### **Research area**

Obstetrics, gynaecology and reproductive medicine (Standard för svensk indelning av forskningsämnen 2011)

#### Keywords

Endometriosis, Melatonin

## **Publications**

Soderman, L., Böttiger, Y., Edlund, M., Jaernbert-Pettersson, H., & Marions, L. (2023). Adjuvant use of melatonin for pain management in endometriosis-associated pelvic pain-A randomized doubleblinded, placebo-controlled trial. In PLOS ONE (Vol. 18, Issue 6). https://doi.org/10.1371/journal.pone.0286182 **DOI:** https://doi.org/10.1371/journal.pone.0286182 **SwePub:** oai:DiVA.org:liu-196852

#### Accessibility level

Access to data through SND Access to data is restricted

## Use of data

Things to consider when using data shared through SND

## Versions

Version 1. 2023-03-24

#### Download metadata

DataCite DDI 2.5 DDI 3.3 DCAT-AP-SE 2.0 JSON-LD PDF Citation (CSL)

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