

INPLASY PROTOCOL

Effect of melatonin for the management of endometriosis: a protocol of systematic review and meta-analysis

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Chen, P¹; Zhao, DX²; Chen, L³; Su, CH⁴; Ji, YJ⁵; Wang DW⁶.

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Corresponding author:
Dong-wei Wang

Dong-weiWang2001@outlook.com

Author Affiliation: First Affiliated Hospital of Jiamusi University

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: No.

Review question / Objective: Does melatonin effective for the management of endometriosis?

Condition being studied: Melatonin , AND endometriosis.

Information sources: Electronic databases (Cochrane Library, MEDLINE, EMBASE, CINAHL, Web of Science, Scopus, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge In-frastructure) will be searched from their inceptions until February 29, 2020 with no language and publication time restrictions. The search strategy for Cochrane Library is presented. We will modify equivalent search strategies for other electronic databases. This study will search other literature sources, such as Google Scholar, conference abstract, and reference lists of all included studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040093).

INTRODUCTION

Review question / Objective: Does melatonin effective for the management of endometriosis?

Condition being studied: Melatonin , AND endometriosis.

METHODS

Participant or population: This study will include patients who were diagnosed as endometriosis or normal participants without restrictions to the race, age, and gender.

Intervention: All studies utilized melatonin alone will be included in the intervention group.

Comparator: All studies used any other management, except melatonin will be included in the control group.

Study designs to be included: We will include randomized controlled trials (RCTs) that investigated the effect of melatonin for the management of endometriosis.

Eligibility criteria: We will include randomized controlled trials (RCTs) that investigated the effect of melatonin for the management of endometriosis. No language and publication time limitations will be applied in this study.

Information sources: Electronic databases (Cochrane Library, MEDLINE, EMBASE, CINAHL, Web of Science, Scopus, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure) will be searched from their inception until February 29, 2020 with no language and publication time restrictions. The search strategy for Cochrane Library is presented. We will modify equivalent search strategies for other electronic databases. This study will search other literature sources, such as Google Scholar, conference abstract, and reference lists of all included studies.

Main outcome(s): Primary outcomes are endometriosis cytokines (including Bcl-2, Fas, ICAM-1), as measured by immunohistochemistry; and natural killer cell activity, as detected by MTT Assay Kit. Secondary outcomes are serum levels of Tumor Necrosis Factor- α , Interleukin-6, and Interleukin IL-8.

Data management: Two researchers will separately extract the following information: title, first author, year of publication, patient characteristics, study methods, study setting, details of intervention and controls (e.g. types of delivery, dosage, and frequency), outcomes, adverse events, results, findings, and funding information. Any conflicts between two researchers will be cleared up by discussion with a third researcher help. We will contact original

authors to request any missing or unclear data, and we will use intention-to-treat analysis for data analysis if we can not achieve that data.

Quality assessment / Risk of bias analysis: Risk of bias for each included study will be appraised by two independent researchers through Cochrane risk of bias tool. It consists of 7 domains, and each one is graded as low, unclear, or high risk of bias. If any different views will be identified between both of them, we will invite a third researcher to solve them through discussion.

Strategy of data synthesis: This study will use RevMan 5.3 software to perform statistical analysis. We will estimate continuous data as weighted mean difference or standardized mean difference and 95% confidence intervals (CIs), dichotomous data as risk ratio and 95% CIs. We will identify statistical heterogeneity by I^2 test. In accordance with the statistical heterogeneity levels among eligible studies, a fixed-effects model ($I^2 \leq 50\%$) or a random-effects model ($I^2 > 50\%$) will be applied to pool the extracted outcome data. If $I^2 \leq 50\%$, we will carry out a meta-analysis. Otherwise, if $I^2 > 50\%$, we will perform a subgroup analysis or sensitivity analysis to find possible sources from clinical and methodological aspects.

Subgroup analysis: If necessary, we will carry out a subgroup analysis based on the study characteristics, details of treatment and controls, and outcomes.

Sensitivity analysis: Whenever necessary, we will also conduct a sensitivity analysis to test stability of results according to the sample size, and study quality.

Country(ies) involved: China.

Keywords: Endometriosis; melatonin; effect.