INPLASY PROTOCOL

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

Conflicts of interest:
None.

Perioperative melatonin use for postoperative outcomes: A systematic review and meta-analysis

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Review question / Objective: **It is highly controversial whether perioperative melatonin use can improve patients' postoperative outcomes including adverse events and perioperative complications.**
Condition being studied: **Studies have found that melatonin has hypnotic, anti-anxiety, pain relief, anti-inflammatory and antioxidant effects. Since it has rarely reported serious adverse effects, melatonin is considered to be a potentially effective perioperative drug, especially in improving postoperative outcomes in surgical patients.**
Information sources: **Databases including PubMed, EMBASE, and Cochrane Library from inception to May 2020.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2020 and was last updated on 26 April 2020 (registration number INPLASY202040184).

INTRODUCTION

Review question / Objective: **It is highly controversial whether perioperative melatonin use can improve patients' postoperative outcomes including adverse events and perioperative complications.**

Condition being studied: **Studies have found that melatonin has hypnotic, anti-anxiety, pain relief, anti-inflammatory and antioxidant effects. Since it has rarely reported serious adverse effects, melatonin is considered to be a potentially effective perioperative drug, especially in improving postoperative outcomes in surgical patients.**

METHODS

Search strategy: **PubMed, EMBASE, and Cochrane Library from inception to May**

2020 will be searched using the terms "melatonin", "N-acetyl-5-methoxytryptamine" and "intraoperat* or perioperat* or peroperat* or postoperat* or preoperat* or premedicat*". Additional search will be conducted through reviewing the list of articles retrieved. No restrictions on language or publication date will be applied during the literature search process.

Participant or population: Adult patients undergoing surgery.

Intervention: Preoperative or perioperative melatonin use.

Comparator: No melatonin use preoperatively or perioperatively.

Study designs to be included: Randomized controlled trials and prospective cohort studies.

Eligibility criteria: We will include studies that compared perioperative complication, anesthesia or safety related outcomes for patients with melatonin use to those without melatonin use.

Information sources: Databases including PubMed, EMBASE, and Cochrane Library from inception to May 2020.

Main outcome(s): Complication, anesthesia or safety related outcomes will be included. For dichotomous outcomes, the Mantel-Haenszel method will be applied to pool odds ratios (ORs)/relative risks (RRs). Continuous variables reported as median and interquartile range will be converted to mean and standard deviation for meta-analysis using the reported approaches. For survival data or outcomes, we will use the inverse variance technique for meta-analysis of hazard ratios (HRs).

Additional outcome(s): None.

Quality assessment /Risk of bias analysis: Cochrane risk of bias assessment tool for RCTs and the Newcastle–Ottawa Scale (NOS) for cohort studies will be applied for risk of bias assessment.

Strategy of data synthesis: Data were analyzed by the STATA 162.0 (Stata Corp, College Station, TX, USA) and RevMan 5.3 (Nordic Cochrane Center, Copenhagen, Denmark). We will apply a random-effects model to combined dichotomous outcomes and continuous outcomes using RRs/ORs and standardised mean differences (SMDs) with their corresponding 95% confidence intervals (95% CI). I^2 statistics will be quantified for heterogeneity assessment for each main outcome. Publication bias will be assessed using Begg's and Egger's test.

Subgroup analysis: To explore the sources of heterogeneity, we will carry out preplanned subgroup analyses according to trial design, geographical regions, patient features, risk of bias, etc.

Sensibility analysis: Sensitivity analysis will be conducted using leave-one-out approach for each study outcome.

Language: Language limits will not be imposed on the literature search.

Country(ies) involved: China.

Keywords: melatonin; perioperative; outcome; randomized controlled trial; cohort.

Contributions of each author:
Author 1 - Hang Yu - Author 1 will conduct literature search, screening, data abstraction, analysis and write the manuscript.
Author 2 - Shouchao Zhu - Author 2 will conduct literature search, screening, data abstraction and analysis.
Author 3 - Xue Wang - Author 3 will conduct literature search, screening, data abstraction and analysis.
Author 4 - Tian Li - Author 4 designed the study and will conduct literature search, screening, data abstraction, analysis and revise the study.
Author 5 - Zubing Mei - Author 5 designed the study and will conduct literature search, screening, data abstraction, analysis, revise the study and write the manuscript.