

# INPLASY

## The efficacy of melatonin and its agonists in treating ICU patients with delirium: a systematic review and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Data analysis.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202620019

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 5 February 2026 and was last updated on 5 February 2026.

### INTRODUCTION

**Review question / Objective** We conducted a meta-analysis to compare the effect of melatonin and its agonists in preventing delirium in ICU patients.

**Condition being studied** The evaluation metrics included the incidence of delirium, duration of delirium, postoperative delirium, ICU length of stay, mortality rate, and total hospital length of stay.

### METHODS

**Participant or population** Adult ICU inpatients

**Intervention** Melatonin and its agonists.

**Comparator** Placebo.

**Study designs to be included** The search strategy was RCTs.

**Eligibility criteria** (1) Adult ICU inpatients; (2) Intervention: oral administration of melatonin(0.3-10mg/d ) or its agonist ramelteon (8mg/d); (3) Outcomemeasures: delirium occurrence (mandatory), plus at least one of the following: time to delirium onset, length of ICU stay, ICU mortality, total hospital stay.

**Information sources** A comprehensive manual search of the PubMed, Embase and Cochrane databases was conducted in order to select relevant randomised controlled trials. Should the necessity arise to obtain pertinent research data, the authors will be duly contacted.

**Main outcome(s)** Incidence of delirium, duration of delirium, postoperative delirium, ICU length of stay, mortality rate, and total hospital length of stay.

**Quality assessment / Risk of bias analysis** We evaluated the methodological quality of the individual studies using the Cochrane risk of bias tool for RCTs.

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**Strategy of data synthesis** For the discontinuous outcomes, relative risk (RR) and 95% CIs were estimated as effective. For the continuous outcomes, mean differences (MD) and 95% CIs were estimated as effective.

**Subgroup analysis** We will conduct the following pre-specified subgroup analyses: 1. Based on drug dosage, including melatonin 3 mg, melatonin at other doses, and melatonin receptor agonists; 2. Based on outcome measures, including the incidence of delirium, duration of delirium, and length of ICU stay, mortality rate, and total hospital length of stay.

**Sensitivity analysis** We conducted sensitivity analyses to investigate the influence of a single study on the overall pooled estimate of each predefined outcome.

**Country(ies) involved** China.

**Keywords** Melatonin, Agonist, Delirium, ICU, Efficacy.

**Contributions of each author**

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