

INPLASY PROTOCOL

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None declared.

Effect of melatonin on blood pressure and heart rates: a systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: Patients with hypertension are at higher risk for cardiovascular and cerebrovascular risk events such as stroke and ischemic heart disease. The meta-analysis of the efficacy and safety of exogenous melatonin in ameliorating blood pressure and heart rate was performed using a random effects model of all studies fitting the inclusion criteria.

Condition being studied: Evidence from the last few years suggests that melatonin may influence the cardiovascular system in humans. Many studies have evaluated the effects of melatonin on nocturnal blood pressure. But the results were not consistent, as in some studies melatonin reduced, and in some it did not, or even increased nocturnal blood pressure. Therefore, we ready to conduct a meta-analysis to assess the effect of melatonin on nocturnal blood pressure.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 May 2022 and was last updated on 05 May 2022 (registration number INPLASY202250033).

INTRODUCTION

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METHODS

Participant or population: Patients with hypertension, with or without drug treatment; normotensive adult.

Intervention: Melatonin.

Comparator: Placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Two researches independently assessed the eligibility of the literature according to the inclusion criteria. All discrepancies were resolved through discussion or by a third researcher as necessary.

Information sources: Pubmed; MEDLINE; web of science; China Academic Journal Network Publishing Database; Cochrane Library; EMBASE.

Main outcome(s): Meta analysis was performed to demonstrate whether melatonin has antihypertensive effect. Main outcomes contain 24-hour, daytime and nighttime systolic and diastolic blood pressure, dipping and non-dipping status, heart rate, sleep quality.

Quality assessment / Risk of bias analysis: The quality assessments will are conducted through Cochrane risk of bias tool.

Strategy of data synthesis: All meta-analysis will be conducted using review manager 5.4 or Stata 12.0. The primary outcomes will be the weighted mean differences in daytime/nighttime/24-hour SBP and DBP and heart rate by 24-h ambulatory blood pressure monitoring.

Subgroup analysis: If necessary, we will carry out a subgroup analysis based on the study characteristics, details of treatment and controls, and outcomes, such as: age/sex/preparation of melatonin (immediate release or controlled release)/dose of melatonin and so on.

Sensitivity analysis: The sensitivity analysis was conducted to determine that whether one of the included studies has the decisive effect on the pooled results. The sensitivity analysis will be conducted by using review manager 5.4 or Stata 12.0.

Country(ies) involved: China.

Keywords: Melatonin, hypertension, SBP, DBP, Circadian rhythm.

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