# INPLASY PROTOCOL

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

**Conflicts of interest:**
**None declared.**

# Safety and efficacy of auricular plaster therapy in patients with insomnia after percutaneous coronary intervention
## A protocol for systematic review and meta-analysis

Shi, YY[1]; Li, CZ[2]; Qu, WT[3]; Zhang, ZP[4]; Chen, Y[5].

**Review question / Objective:** **P: Insomnia after PCI; I: Auricular plaster; C: Conventional western medicine is the only treatment; O: The main results were the scores of insomnia severity index (LSI) and Pittsburgh sleep quality index(PSQI) scores and Athens insomnia scale(AIS) scores.The secondary results of this review mainly include the following aspects: 1. All cause death, heart death. 2. Major adverse cardiovascular events (MACE). 3. Rehospitalization rate. 4. Quality of life scale (SF-36). Effective rate and incidence of adverse events; S: All relevant Chinese and English randomized controlled trials (RCTs) will be included. Although non randomized controlled trials, quasi randomized controlled trials, cohort studies, reviews, case reports, experimental studies and expert experience, the data included in the study are missing or incomplete, and duplicate publications will be excluded to ensure the quality of the review of the system.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 March 2022 and was last updated on 31 March 2022 (registration number INPLASY202230177).

## INTRODUCTION

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**Rationale:** Percutaneous coronary intervention (PCI) has the advantages of less injury and the best curative effect. It has been implemented in a large number of patients with coronary artery disease (CAD). Many studies have shown that the prevalence of insomnia after PCI is increased and the long-term prognosis is poor. Anti insomnia drugs have potential side effects, such as sexual dysfunction, weight change and sleep interruption. Auricular plaster is effective for insomnia. As a form of traditional Chinese medicine physiotherapy, auricular plaster has been used to alleviate the symptoms of insomnia patients after PCI, but its effectiveness and safety have not been clearly concluded. Therefore, this systematic review and meta-analysis program aims to evaluate the efficacy and safety of auricular plaster therapy in patients with insomnia after PCI.

**Condition being studied:** Percutaneous coronary intervention (PCI), as an effective revascularization strategy, has been more and more used in patients with coronary heart disease (CAD). However, recent studies have shown that the incidence of insomnia is higher in patients after PCI. At present, the drug treatment of insomnia after PCI is difficult to achieve satisfactory results, and the side effects are obvious. Auricular plaster is effective in the treatment of insomnia. As a form of TCM physiotherapy, auricular plaster has been used to alleviate the symptoms of insomnia patients after PCI, but its effectiveness and safety have not been clearly concluded. Therefore, this systematic review and meta-analysis program aims to evaluate the efficacy and safety of insomnia after auricular plaster PCI.

## METHODS

**Search strategy:** PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, China biomedical literature database, Wan-fang and Chinese Scientific and Technological Journal Database will be searched to collect randomized controlled trials (RCTs) of auricular plaster in the treatment of insomnia after PCI.The range of publication time will be from the inception of the database to March 2022 without language limitation.

**Participant or population:** Insomnia after percutaneous coronary intervention.

**Intervention:** Auricular plaster.

**Comparator:** Conventional western medicine is the only treatment.

**Study designs to be included:** All relevant Chinese and English randomized controlled trials (RCTs) will be included.

**Eligibility criteria:** Participants who suffer from insomnia after PCI will be included without restrictions on nationality, age, gender and race.

**Information sources:** PubMed, Embase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, China biomedical literature database, Wan-fang and Chinese Scientific and Technological Journal Database.

**Main outcome(s):** The main results were the scores of insomnia severity index (LSI) and Pittsburgh sleep quality index(PSQI) scores and Athens insomnia scale(AIS) scores.

**Additional outcome(s):** 1. All cause death, heart death. 2. Major adverse cardiovascular events (MACE). 3. Rehospitalization rate. 4. Quality of life scale (SF-36). Effective rate and incidence of adverse events.

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**Data management:** Data extraction will be conducted by two reviewers independently.A standard data extraction table will be designed according to Cochrane guidelines, including first authors name, country of publication, year of publication, title of journal, study design,patient information, intervention, control, duration of intervention, the effects of insomnia symptoms, including changes in insomnia severity index(ISI) scores, Pittsburgh sleep quality index(PSQI) scores and Athens insomnia scale(AIS) scores.Any disagreement about the data extraction will be resolved by discussion with the third reviewer. If some important information is missing, we will contact original authors by email to request detailed information about the research.

**Quality assessment / Risk of bias analysis:** Two reviewers evaluated the methodological quality of the included trials according to the Cochrane Risk of Bias tool.We evaluated random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. The bias of the study will be rated on 3 levels: “high,” “unclear,” or “low.”Any disagreement about assessment of risk of bias will be resolved by discussion with the third reviewer.

**Strategy of data synthesis:** Review Manager Software 5.3 will be used for data synthesis. Risk ratio will be used for dichotomous outcomes with 95% confidence interval. The random effects model or fixed effects model will be selected according to the I2 value.The heterogeneity will be examined using the I2 test. The I2value > 50% means significant heterogeneity, and the random effects model will be used. I2value ≤50% means minor heterogeneity, and the fixed effects model will be utilized. If significant heterogeneity still exists after subgroup analysis, meta-analysis will not be pooled, and descriptive summary will be reported.

**Subgroup analysis:** Subgroup analysis will be performed based on the intervention time.

**Sensitivity analysis:** Sensitivity analysis will be applied to check the robustness and reliability of pooled results. We will perform meta-analysis again after eliminating studies in low quality and will apply different statistical methods.

**Country(ies) involved:** China.

**Keywords:** insomnia, auricular plaster, coronary artery disease, percutaneous coronary intervention, protocol, systematic review.

**Contributions of each author:**

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