INPLASY PROTOCOL

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

Conflicts of interest:
None.

Adverse reactions of vancomycin in humans: a protocol for meta-analysis

Peng, Y[1]; Li, CY[2]; Yang, ZL[3]; Shi, W[4].

Review question / Objective: **What are the adverse reactions of vancomycin?**
Condition being studied: **Adverse reaction; vancomycin; human.**
Information sources: **The following electronic databases will be searched: PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure, Chinese Biomedical Literature Database, and China Science and Technology Journal Database. The range of publication time will be from the inception of the database to August 2020 without language limitation. The detailed search strategy of PubMed will be created. The similar search strategies will be used for other electronic databases.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2020 and was last updated on 22 August 2020 (registration number INPLASY202080094).

INTRODUCTION

Review question / Objective: **What are the adverse reactions of vancomycin?**

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METHODS

Participant or population: **Participants who received vancomycin therapy will be included without restrictions of age, gender, and race.**

Intervention: **In the experimental group, patients were given vancomycin with no limitations of administration routes, frequency and treatment period.**

Comparator: **In the control group, no limitations were applied to the control treatments. However, studies used the**

combination of vancomycin and other treatments will not be included.

Study designs to be included: Only randomized controlled trials (RCTs) on clinical application of vancomycin will be considered without language limitation. Case reports, reviews, non-RCTs and animal experiments will be excluded.

Eligibility criteria: This study will include RCTs that record the incidence of adverse reactions of vancomycin.

Information sources: The following electronic databases will be searched: PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure, Chinese Biomedical Literature Database, and China Science and Technology Journal Database. The range of publication time will be from the inception of the database to August 2020 without language limitation. The detailed search strategy of PubMed will be created. The similar search strategies will be used for other electronic databases.

Main outcome(s): The incidence of adverse reactions (such as hypersensitivity reactions, nephrotoxicity, ototoxicity, phlebitis and agranulocytosis) will be designated as the outcomes.

Data management: After selection, two reviewers will independently conduct data extraction. Any confusion 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. The general information will be extracted, including first author's name, country of publication, year of publication, title of journal, study design, patient information, experimental and control intervention (drug names, administration routes, dose, frequency and treatment period), and specific details about adverse events (symptoms and number of persons experiencing an adverse reaction).

Quality assessment / Risk of bias analysis: Risk of bias of the selected studies will be assessed by the Cochrane risk of bias assessment tool. This tool covers seven aspects: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. A bias value of 'high', 'unclear', or 'low' was given for each item. These seven items were assessed independently by two reviews. Any divergences will be resolved by discussion with the third reviewer.

Strategy of data synthesis: Review Manager 5.3 will be used for data synthesis. Odds ratio will be used for dichotomous outcomes with 95% confidence interval. Heterogeneity will be examined using the I2 test. The I2 value > 50% means significant heterogeneity, and the random effects model will be used. Otherwise, the I2 value ≤ 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 to check the potential heterogeneity and inconsistency based on the different participant characteristics, administration routes and dose of vancomycin, control methods, and outcome measurements.

Sensibility analysis: Sensitivity analysis will be conducted to check the robustness and reliability of pooled outcome results by excluding low-quality studies and small studies.

Country(ies) involved: China.

Keywords: adverse reaction, vancomycin; protocol; meta-analysis; human.

Contributions of each author:
Author 1 - Yang Peng.
Author 2 - Chen-yang Li.
Author 3 - Zhi-ling Yang.
Author 4 - Wei Shi.