

INPLASY PROTOCOL

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

Conflicts of interest:
None.

Efficacy and safety of pasireotide for Cushing's disease: A protocol for systematic review and meta-analysis

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Review question / Objective: To systematically evaluate the efficacy and safety of pasireotide for Cushing' disease (CD).
Condition being studied: Pasireotide, Cushing's disease, protocol, systematic review, meta-analysis.

Information sources: Five English databases (PubMed, Web of Science, Embase, Cochrane Library, and OVID) and three Chinese databases (China National Knowledge Infrastructure, China Science and Technology Journal Database, and Chinese Biomedical Literature Database) will be searched from their respective inception of databases to December 2020. Additional trials will be searched by reviewing the reference lists of the retrieved articles, conference proceedings, and gray literature. The detailed search strategy for PubMed is shown in the final manuscript. 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 17 November 2020 and was last updated on 17 November 2020 (registration number INPLASY2020110070).

INTRODUCTION

Review question / Objective: To systematically evaluate the efficacy and safety of pasireotide for Cushing' disease (CD).

Condition being studied: pasireotide, Cushing's disease, protocol, systematic review, meta-analysis.

METHODS

Participant or population: Participants who are diagnosed with CD regardless of nationality, age, gender, and race will be included.

Intervention: In treatment group, patients were given pasireotide with no limitations of administration routes, dosage or duration of intervention.

Comparator: In control group, patients were given conventional treatments, placebo therapy, or no treatment.

Study designs to be included: All available randomized controlled trials (RCTs) of pasireotide for CD will be included, while case reports, animal experiments and reviews will be excluded.

Eligibility criteria: RCTs of pasireotide for CD.

Information sources: Five English databases (PubMed, Web of Science, Embase, Cochrane Library, and OVID) and three Chinese databases (China National Knowledge Infrastructure, China Science and Technology Journal Database, and Chinese Biomedical Literature Database) will be searched from their respective inception of databases to December 2020. Additional trials will be searched by reviewing the reference lists of the retrieved articles, conference proceedings, and gray literature. The detailed search strategy for PubMed is shown in Table 1. The similar search strategies will be used for other electronic databases.

Main outcome(s): The primary outcome contains mUFC and the percentage of cortisol normalization.

Additional outcome(s): Mean fasting glucose, glycated haemoglobin and drug-related adverse events will be designated as the secondary outcome.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias assessment tool will be used by two reviewers indepen-

dently to evaluate the bias risk of the subsequent areas of all included studies: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias. Disagreement will be solved by the third reviewer. Bias graph and graphic summary of risk of bias will be provided in the completed review.

Strategy of data synthesis: Review Manager 5.3 software will be used for data synthesis. Standardized mean difference or mean difference with 95% confidence interval will be used for continuous variables, and risk ratio with 95% confidence interval will be used for dichotomous variables. We will use I² test to identify heterogeneity. The I² value > 50% means significant heterogeneity, and the random effects model will be utilized. The I² value ≤ 50% means acceptable heterogeneity, and the fixed effects model will be utilized.

Subgroup analysis: Subgroup analysis will be carried out based on different participant characteristics, administration routes, dosage and duration of intervention, and outcome assessments to explore any possible sources of significant heterogeneity among included trials.

Sensibility analysis: Sensitivity analysis will be carried out to test the robustness and stability of data analysis by repeated meta-analysis after eliminating low quality studies.

Country(ies) involved: China.

Keywords: pasireotide, Cushing's disease, protocol, systematic review, meta-analysis.

Contributions of each author:

Author 1 - Nairui Zhao.

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Author 4 - Jie Ma.

Author 5 - Xiuping Yin.