

INPLASY PROTOCOL

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

Conflicts of interest: None.

Does benralizumab effectively treat chronic obstructive pulmonary disease? a protocol of systematic review and meta-analysis

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Review question / Objective: Does benralizumab effectively and safely treat chronic obstructive pulmonary disease (COPD)?

Condition being studied: Chronic obstructive pulmonary disease and benralizumab.

Information sources: Electronic database records searches Electronic searches will be performed systematically and comprehensively for relevant studies in (MEDLINE, EMBASE, Cochrane Library, Global health, PsycINFO, Scopus, WANGFANG, and CNKI). All these databases will be conducted from inception to the present regardless their language and publication time. A search strategy sample of MEDLINE will be created. Similar search strategies will be adapted and applied to other electronic databases. Searching other records source To avoid missing potential studies, other records source will be identified, such as conference abstracts, dissertations, and reference lists of included studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2020 and was last updated on 07 April 2020 (registration number INPLASY202040039).

INTRODUCTION

Review question / Objective: Does benralizumab effectively and safely treat chronic obstructive pulmonary disease (COPD)?

Condition being studied: Chronic obstructive pulmonary disease and benralizumab.

METHODS

Participant or population: Any patients who were diagnosed as COPD will be included in spite of sex, age, severity of COPD.

Intervention: In the experimental group, all patients received benralizumab treatment will be included.

Comparator: In the control group, all patients received any management without restrictions. However, if we identified any study which involved benralizumab as their comparator, we will exclude it.

Study designs to be included: Only randomized controlled trials (RCTs) of benralizumab for the treatment of COPD will be included.

Eligibility criteria: This study will include RCTs that compared the efficacy and safety of benralizumab with other treatments for the treatment of COPD.

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Main outcome(s): Primary outcome is lung function, which was measured by forced vital capacity or forced expiratory volume in one second or other relevant tools.

Additional outcome(s): Secondary outcomes are proportion of participants who had COPD exacerbation, rescue medication use, 6-minute walk test,

dyspnea levels, quality of life (as measured by Saint George Respiratory Questionnaire or other tools), and adverse events.

Data management: Two reviewers will independently extract data based on the predefined data extraction sheet. A third reviewer will help to solve any discrepancies through discussion. We will collect data of title, first author, year of publication, region, race, gender, diagnostic criteria, eligibility criteria, trial setting, trial methods, details of interventions and controls, outcome indicators, results, findings, adverse events, follow-up information, and conflict of interest.

Quality assessment / Risk of bias analysis: Two reviewers will independently appraise study quality of all included trials using Cochrane Risk of Bias Tool, which covers 7 items, and each one is rated as low, unclear and high risk of bias. We will invite a third reviewer to solve any different opinions by discussion.

Strategy of data synthesis: RevMan 5.3 software will be utilized for performing statistical analysis. All discontinuous outcome variations will be estimated using risk ratio and 95% confidence intervals (CIs), and all continuous outcome variations will be calculated using weighted mean difference or standardized mean difference and 95% CIs. Statistical heterogeneity among included trials using I^2 test: $I^2 \leq 50\%$ means minor heterogeneity, while $I^2 > 50\%$ suggests considerable heterogeneity. A fixed-effects model will be applied to pool the data if $I^2 \leq 50\%$. On the other hand, a random-effects model will be used to synthesize the data if $I^2 > 50\%$. When necessary, we will conduct a meta-analysis based on the similarity in study and patient characteristics, interventions and controls, and outcome indicators. If we identified obvious heterogeneity, we will undertake a subgroup analysis to investigate possible sources of heterogeneity. In addition, we will also report study results using narrative summary descriptions.

Subgroup analysis: A subgroup analysis will be investigated to explore the possible sources of heterogeneity according to the different study characteristics, interventions, controls and outcomes.

Sensibility analysis: A sensitivity analysis will be examined to check robustness and stability of study findings by eliminating low quality studies.

Country(ies) involved: China.

Keywords: Chronic obstructive pulmonary disease; benralizumab; efficacy; safety.