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A systematic review of abatacept and belatacept in autoimmune disease

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024110072

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 November 2024 and was last updated on 17 November 2024.

INTRODUCTION

Review question / Objective This study systematically reviews clinical efficacy of abatacept or belatacept use in autoimmune diseases beyond the approved indications (rheumatoid arthritis, juvenile idiopathic arthritis and kidney-transplant) in comparison to placebo or conventional treatments.

Rationale Rare autoimmune diseases as well as immunodeficiencies with secondary autoimmune manifestations are often refractory to immunosuppressive treatments. This systematic review aims at analyzing existing evidence of treatment efficacy in these disease entities.

Condition being studied Autoimmune diseases.

METHODS

Search strategy The Web of Science and PubMed databases will be searched for publications reporting clinical application of abatacept or belatacept in patients with autoimmunity, excluding patients with rheumatoid arthritis and juvenile idiopathic arthritis. We will include clinical trials, case series, and case reports. The searches will be filtered to include reviews, articles, clinical trials and case reports.

Participant or population Patients suffering from autoimmune disease.

Intervention Treatment with abatacept or belatacept.

Comparator Placebo or standard-of care treatment.

Study designs to be included Randomized controlled trials (RCTs), their extension trials and subgroup analysis, case series and case reports, and non-randomized controlled trials.

Eligibility criteria Clinical trials, case series or case reports using abatacept or belatacept in autoimmune disease.

Information sources Web of Science and PubMed databases.

Main outcome(s) Clinical efficacy of abatacept or belatacept in comparison to placebo or standard-of care treatment from baseline to last available follow-up.

Data management We will use EndNote to manage literature and extract data to an Excel spreadsheet.

Quality assessment / Risk of bias analysis Modified Downs and Black assessment for risk of bias.

Strategy of data synthesis We will conduct a search of abatacept and belatacept use in autoimmune disease in the Web of Science and PubMed database in all available articles and also for each specific autoimmune disease separately. Since we want to give an overview including rare diseases we do not specify in more detail the endpoints in order to not exclude potentially important studies.
Two authors will independently conduct the primary search using the predefined search terms and screen for clinical trials and case series/ reports testing the use of Abatacept or Belatacept in various autoimmune diseases. The lists will then be compared and any disagreement of study inclusion will be resolved by consensus. If consensus cannot be reached, a third author will be consulted.
We will list all included study results of Abatacept and Belatacept use in different autoimmune diseases to be able to give an overview of its efficacy including in rare diseases and to be able to make recommendations regarding future therapeutic use.

Subgroup analysis Subgroup analysis will be applied for each autoimmune disease.

Sensitivity analysis We will conduct a preliminary search of abatacept and belatacept use in autoimmune disease in the Web of Science and PubMed database in all available articles. We then create our detailed search terms list to make sure to include rare diseases. We thus expect high sensitivity to meet our outcome of this study.

Language restriction English.

Country(ies) involved Switzerland.

Keywords Abatacept, Belatacept, CTLA-4 Ig, autoimmune diseases, systematic review.

Dissemination plans We aim to publish our results in a peer-reviewed journal.

Contributions of each author

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