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The efficacy and safety of Cadonilimab in patients with recurrent/metastatic cervical cancer: a single-arm meta-analysis and systematic review

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ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 December 2024 and was last updated on 14 December 2024.

INTRODUCTION

Review question / Objective Recurrent or metastatic cervical cancer (R/M CC) poses significant health challenges and economic burdens, necessitating the exploration of novel therapeutic approaches. This study aimed to evaluate the efficacy and safety of cadonilimab, a PD-1/CTLA-4 bispecific antibody, in treating patients with cervical cancer.

Condition being studied Cadonilimab, developed by Kangfang Biotech with the research code AK104, is a novel tumor immunotherapy drug that functions as a PD-1/CTLA-4 bispecific antibody. Primarily indicated for the treatment of recurrent or metastatic cervical squamous cell carcinoma after standard therapy, Cadonilimab is also being investigated for its potential in treating other cancers such as liver, gastric, lung, esophageal squamous cell, and nasopharyngeal cancers. The drug has advanced through clinical trials, including a registrational Phase II trial in China for recurrent or metastatic cervical cancer, which has completed patient screening and enrollment. Additionally, Cadonilimab has been granted Fast Track Designation (FTD) by the U.S. Food and Drug Administration (FDA) for the same indication. In separate studies, it is being evaluated as a neoadjuvant therapy for microsatellite instability-high (MSI-H) advanced solid tumors, showing promising early clinical data in terms of efficacy and safety. Cadonilimab has been marketed in China for the treatment of cervical cancer.

METHODS

Participant or population Patients with recurrent/metastatic cervical cancer.

Intervention Patients were treated with Cadonilimab,either with single-agent therapy or in combination with chemotherapy.

Comparator No.

Study designs to be included single-arm meta-analysis.

Eligibility criteria Animal experiments, cell research,reviews, meta-analyses, duplicates, case report or letters were not in consideration; studies with patients number less than 10 were excluded.

Information sources The required data from all included studies were independently extracted by two investigators, and the quality assessment of the studies was performed afterwards.The extracted characteristics weresummarized as following: authors,publication year, nation, sample size, priortherapeutic regimen, median age, medianfollow-up and reported endpoints. Indexes for clinical and safety outcomes included ORR, DCR, the incidence of any AEs and zgrade 3 AEs. Also, two investigators independently assessed andextracted the required data from all included studies.

Main outcome(s) Overall response rate(ORR), Diseasecontrol rate(DCR).

Additional outcome(s) Adverse events(AEs).

Quality assessment / Risk of bias analysis The Newcastle-0ttawa Scale(NOS)was used to evaluate the quality of includingnon-controlled trials. The retrospective studies were assessed by JBI CriticalAppraisal Checklist for Case Series.

Strategy of data synthesis All data in thismeta-analysis were analyzed with STATA14.2 software(Stata Corp LP, CollegeStation, TX,USA).Heterogeneity wasmeasured using the Chi-square test and12statistic.P<0.1 indicated a statisticallysignificant difference. If significant heterogeneity(P-value 50%)existed, random-effect model was performed.Otherwise,the fixed-effects model was used. Potential publication bias wasaccessed by Begg's and Egger'stests.

Subgroup analysis Cadonilimab as monotherapy of combination therapy.

Sensitivity analysis Sensitivity analysis was performed to analyze the stability andreliability of the pooled results.

Country(ies) involved China.

Keywords cadonilimab ; PD-1/PD-L1; CTLA-4; combination therapy; meta-analysis; recurrent or metastatic cervical cancer (R/M CC).

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