INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Recombinant human adenovirus-p53 therapy for the treatment of cervical cancer : a meta-analysis

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Review question / Objective: **To compare clinical curative effects and toxicity of recombinant human adenovirus-p53 injection (rAd-p53) combining chemotherapy(CT)/radiotherapy (RT)/chemoradiotherapy (CRT) with those obtained with CT/RT/CRT alone in cervical cancer.**
Condition being studied: **We searched all the eligible studies of chemotherapy or radiotherapy plus Recombinant human adenovirusp53 versus control group without Recombinant human adenovirus-p53 in the treatment of cervical cancer, which were retrieved from CNKI, Wanfangdate, CBM, VIP, PubMed, EMBase, Meta-analysis was con-ducted by RevMan5.3 soft ware after date extraction and quality evaluation by the Cochrane Collaboration's tool for randomized controlled trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2021 and was last updated on 16 May 2021 (registration number INPLASY202150058).

INTRODUCTION

Review question / Objective: **To compare clinical curative effects and toxicity of recombinant human adenovirus-p53 injection (rAd-p53) combining chemotherapy(CT)/radiotherapy (RT)/chemoradiotherapy (CRT) with those obtained with CT/RT/CRT alone in cervical cancer.**

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METHODS

Search strategy: Collect randomized clinical controlled studies (RCT) of chemotherapy or radiotherapy plus Recombinant human adenovirus-p53 versus control group without Recombinant human adenovirus-p53 in the treatment of cervical cancer, which were retrieved from CNKI Wanfangdate, CBM, VIP, PubMed, EMBase, The cochrance of library, web of science for the deadlines of May 2021.

Participant or population: Patients diagnosed with cervical cancer by histopathological examination and cytological examination.

Intervention: Recombinant human adenovirus-p53 combined with chemotherapy(CT) or radiotherapy(RT) or chemoradiotherapy.

Comparator: Chemotherapy or radiotherapy or chemoradiotherapy.

Study designs to be included: Randomized Controlled Trial.

Eligibility criteria: Patients diagnosed with cervical cancer by histopathological examination and cytological examination.

Information sources: PubMed, EMBase, The Cochrane of library, web of science, CNKI, Wanfangdate, CBM, VIP.

Main outcome(s): Complete response rate(CR),objective response rate, ORR and adverse reactions rate.

Additional outcome(s): DNA ploidy.

Data management: Noteexpress.

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: Random sequence generation (selection Bias) Allocation concealment (selection bias) Blinding of participants and personnel (performance bias) Incomplete outcome data (attrition bias) Selective reporting (reporting bias) Other biases Results from these questions will be graphed and assessed using Review Manager 5.3.

Strategy of data synthesis: All analyses were performed by Review Manager (version 5.3, the Cochrane collaboration), using two side p values. Results were reported as pooled as odds ratio(OR) and their 95% confidence interval (CI). Firstly, heterogeneity was identified. If the heterogeneity was not significant ($p > 0.1$, $I2 < 50.0\%$), then the fixed-effect model can be performed, otherwise, the random effects model. Results of this meta-analysis were presented by forest plots, and the p value less than 0.05 was considered significant. Publication bias was evaluated though funnel plots.

Subgroup analysis: We will consider subgroups such as Recombinant human adenovirus-p53 combined with or chemotherapy or radiotherapy or chemoradiotherapy in treating in cervical cancer.

Sensitivity analysis: The sensitivity analysis was carried out by Stata software, and the sensitivity of the article was reflected by the change of effect size after deleting one of the articles.

Country(ies) involved: China.

Keywords: Cervical cancer; Recombinant human adenovirus-p53 Radiotherapy; chemotherapy; radiotherapy; Chemoradiotherapy.

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