INPLASY PROTOCOL

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Conflicts of interest:
No competing interest exists.

The optimal second-line treatment model for recurrent and/or metastatic head and neck squamous cell carcinoma: a Bayesian network meta-analysis

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Review question / Objective: **The optimal second-line treatment model for recurrent and/or metastatic head and neck squamous cell carcinoma (R/M HNSCC) remains contentious. A Bayesian network meta-analysis would be performed to address this important issue concerning efficacy and toxicity.**
Condition being studied: **This is a network meta-analysis based on the current researches, all required studies are available by searching online databases. And the method involved in this work is well-grasped by the co-authors.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 November 2020 and was last updated on 10 November 2020 (registration number INPLASY2020110041).

INTRODUCTION

Review question / Objective: **The optimal second-line treatment model for recurrent and/or metastatic head and neck squamous cell carcinoma (R/M HNSCC) remains contentious. A Bayesian network meta-analysis would be performed to address this important issue concerning efficacy and toxicity.**

Condition being studied: **This is a network meta-analysis based on the current researches, all required studies are available by searching online databases.**

And the method involved in this work is well-grasped by the co-authors.

METHODS

Participant or population: Patients with recurrent and/or metastatic head and neck squamous cell carcinoma.

Intervention: Second-line systematic treatments, including chemotherapy, targeted therapy or immunotherapy.

Comparator: This is a network meta-analysis, we aim to compare the different treatment models involved in eligible studies.

Study designs to be included: Efficacy demonstrated as overall survival, progression-free survival by hazard ratios and severe acute events demonstrated as ≥grade 3 toxiticity by odds ratios would be assessed, respectively, to compare the different treatment models applying a NMA. Besides, a rank probability would be done in terms of both efficacy and toxicity.

Eligibility criteria: 1. Randomized controlled trials; 2. Pathologically confirmed R/M HNSCC; 3. Containing treatments of chemotherapy, targeted therapy, immunotherapy or a combination of each other; 4. Survival data and/or toxicity profiles were available in the study or through calculating.

Information sources: Eligible studies would be obtained by the following databases: MEDLINE (via PubMed), Embase, Cochrane Central Register of Controlled Trials and Web of Science.

Main outcome(s): Efficacy demonstrated as overall survival, progression-free survival by hazard ratios and severe acute events demonstrated as ≥grade 3 toxiticity by odds ratios were assessed, respectively.

Quality assessment / Risk of bias analysis: The risk of bias of the included RCTs was assessed based on the Cochrane Risk of Bias Tool, which contains 7 domains, namely random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias. Results will be categeried as low, high, or unclear risk of bias.

Strategy of data synthesis: Efficacy outcome assessments are hazard ratios for overall survival/progression-free survival and the safety measures are odds ratios for treatment-related severe acute events, along with their 95% credible intervals. And these collected outcomes insure the data synthesis.

Subgroup analysis: Whenever necessary, subgroup analysis by age, gender, tumor types, immune biomarkers, etc. will be conducted.

Sensibility analysis: Whenever necessary, subgroup analysis by age, gender, tumor types, immune biomarkers, etc. will be conducted.

Country(ies) involved: China.

Keywords: Recurrent, Metastatic, Head and neck squamous cell carcinoma, Network meta-analysis, Second-line treatments.

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