INPLASY PROTOCOL

To cite: Lin et al. Smoking status in the first line treatment of advanced ALK-positive non-small cell lung cancer : a Bayesian network meta-analysis. Inplasy protocol 202180009. doi: 10.37766/inplasy2021.8.0009

Received: 03 August 2021

Published: 03 August 2021

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Support: **Key Clinical Technology of GZ.**

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

Conflicts of interest:
None declared.

Smoking status in the first line treatment of advanced ALK-positive non-small cell lung cancer : a Bayesian network meta-analysis

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Review question / Objective: **Patient: Patients with non-small cell lung cancer(NSCLC) harboring anaplastic lymphoma kinase(ALK) mutation; Intervention: ALK Tyrosine kinase inhibitor(ALK-TKI); Comparison: another ALK-TKI or chemotherapy; Outcomes: progression-free survival (PFS), overall survival (OS); Study design: Randomized controlled trial.**
Condition being studied: **Anaplastic lymphoma kinase-tyrosine kinase inhibitors (ALK-TKIs) have improved the clinical prognosis of ALK-positive NSCLC patients. Studies of these drugs have included populations with or without smoking history; And smoking status, an important clinicopathologic features, has been associated with the presence of an ALK rearrangement. Therefore, We performed this Bayesian network meta-analysis to assess the comparative outcomes of the various ALK-TKIs in smoking and non-smoking patients, respectively.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 August 2021 and was last updated on 03 August 2021 (registration number INPLASY202180009).

INTRODUCTION

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METHODS

Participant or population: Patients with non-small cell lung cancer(NSCLC) harboring anaplastic lymphoma kinase(ALK) mutation.

Intervention: ALK Tyrosine kinase inhibitor(ALK-TKI).

Comparator: Another ALK-TKI or chemotherapy.

Study designs to be included: Any randomized controlled trials(RCTs) involving OS, PFS of TKIs for treating ALK-positive NSCLC will be included.

Eligibility criteria: 1.Randomized controlled trials with clinical outcomes, such as PFS,OS; 2. All included studies had clear baseline characteristics of patients and ALK mutation status; 3. All included studies included subgroup-analysis data required for meta-analysis.

Information sources: Pubmed, Embase, Cochrane Library, Web of Science, clinicalTrials.gov, American Society of Clinical Oncology, European Society of Medical Oncology, and World Conference on Lung Cancer.

Main outcome(s): PFS.

Additional outcome(s): OS.

Quality assessment / Risk of bias analysis: We assess the risk of bias of the included RCTs by using Cochrane Risk of Bias Tool. Results will be categorized as low, high, or unclear risk of bias.

Strategy of data synthesis: Efficacy outcome assessments are hazard ratios for overall survival/progression-free survival, along with their 95% credible intervals. And these collected outcomes insure the data synthesis.

Subgroup analysis: We will consider subgroups such as race, study design.

Sensitivity analysis: If significant heterogeneity exists, sensitivity analysis will be performed.

Country(ies) involved: China.

Keywords: NSCLC; ALK-TKIs; Network meta-analysis; Smoking status.

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