INPLASY PROTOCOL

To cite: Wang et al. Risk of Bleeding Associated With Ibrutinib in Patients With B-Cell Malignancies A Systematic Review and Meta-analysis of Randomized Controlled Trials. Inplasy protocol 202060076. doi: 10.37766/inplasy2020.6.0076

Received: 21 June 2020

Published: 21 June 2020

Corresponding author:
Jinjin Wang

463413034@qq.com

Author Affiliation:
West China Hospital,Sichuan University

Support: **Sichuan University**

Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
The authors declared that they have no conflicts of interest to this work.

Risk of Bleeding Associated With Ibrutinib in Patients With B-Cell Malignancies A Systematic Review and Meta-analysis of Randomized Controlled Trials

Wang, J[1]; Zhou, H[2]; Niu, T[3].

Review question / Objective: **This meta-analysis is performed to systematically estimate the risk of bleeding associated with ibrutinib in patients with B-cell malignancies in randomized controlled trials.**
Condition being studied: **Ibrutinib has been approved for chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/SLL) and some other B-cell malignancies. Some studies have found an increased risk of bleeding with ibrutinib. However, some literatures found no significant differences in the risk of major bleeding in patients treated with ibrutinib compared with other regimens.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 June 2020 and was last updated on 21 June 2020 (registration number INPLASY202060076).

INTRODUCTION

Review question / Objective: **This meta-analysis is performed to systematically estimate the risk of bleeding associated with ibrutinib in patients with B-cell malignancies in randomized controlled trials.**

Condition being studied: **Ibrutinib has been approved for chronic lymphocytic leukemia/small lymphocytic leukemia (CLL/**

SLL) and some other B-cell malignancies. Some studies have found an increased risk of bleeding with ibrutinib. However, some literatures found no significant differences in the risk of major bleeding in patients treated with ibrutinib compared with other regimens.

METHODS

Participant or population: Patients With B-Cell Malignancies.

Intervention: Ibrutinib.

Comparator: Other agents or placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The PICOS-guided eligible criteria included the following: (1) Population (P): patients with B-cell malignancies; (2) Intervention (I): ibrutinib; (3) Outcomes (O): the risk of bleeding ; and (4) Study design (S): randomized controlled trials.

Information sources: We searched PUBMED, EMBASE, Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov.

Main outcome(s): The relative risk of overall and major bleeding.

Quality assessment / Risk of bias analysis: The risk of bias was assessed using Cochrane's Risk of Bias Tool.

Strategy of data synthesis: Data synthesis was performed using RevMan software version 5.3. Bleeding events were pooled with the Mantel-Haenszel method to estimate the relative risk of bleeding.

Subgroup analysis: The relative risk of bleeding in different treatment setting and different dosages of ibrutinib.

Sensibility analysis: Sensitivity analysis was carried out by taking turns to exclude each study thus producing a new analysis to assess the stability of the pooled results.

Country(ies) involved: China.

Keywords: ibrutinib; B-cell malignancies; overall bleeding; major bleeding; risk.

Contributions of each author:
Author 1 - Jinjin Wang.
Author 2 - H Zhou.
Author 3 - T Niu.