INPLASY

The efficacy and safety of regofinib in the treatment of advanced bone and soft tissue sarcoma : a Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - XWRCHT20220056.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110098

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 November 2023 and was last updated on 24 November 2023.

INTRODUCTION

Review question / Objective To explore the efficacy and safety of regofinib in the treatment of advanced bone and soft tissue sarcoma by meta analysis.

Condition being studied For patients with pathologically confirmed advanced bone and/or advanced soft tissue sarcoma (excluding gastrointestinal stromal tumors), the PS score was 0-2, and the number of previous treatment lines was 0-6.

METHODS

Participant or population Patients with pathologically confirmed advanced bone and/or advanced soft tissue sarcoma (excluding gastrointestinal stromal tumors).

Intervention Intervention measures: the experimental group was treated with regofinib.

Comparator The control group was treated with placebo.

Study designs to be included Randomized Controlled Trial.

Eligibility criteria (1) Literature research type: Published RCT. (2) Participants: Patients with pathologically confirmed advanced bone and/or advanced soft tissue sarcoma (excluding gastrointestinal stromal tumors). (3) Intervention measures: the experimental group was treated with regofinib, and the control group was treated with placebo.

Information sources CNKI Wanfangdatabase, CBM, VIP, PubMed, EMBase, Chrance of Library, Web ofScience.

Main outcome(s) ORR, DCR, 3-month PFS rate, 6-month PFS rate, 3-month OS rate, 6-month OS rate and the incidence ofAES.

Data management Noteexpress and excel.

Quality assessment / Risk of bias analysis Two reviewers will independently assess the quality of the included studies.The Cochrane Collaboration's tool was 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.The methodological index(MINORS) was for non-randomized trials, Mainly from the following aspects of evaluation:The purpose of the study is clearly given. Patient coherence was included. Expected datacollection。The endpoints appropriately reflect the purpose of the study. Objective evaluation of end points. Adequate follow-up time. The loss to follow-up was less than 5%. Was the sample size estimated.

Strategy of data synthesis All metaanalyses were performed using Cochrane RevMan version 5.3 and Stata (version 13). The results were reported as pooled odds ratios (ORs) with 95% confidence intervals (95%CIs). We used Cochran's Q test and I2 statistics to evaluate the heterogeneity of all the studies. If the heterogeneity was significant (p 50.0%), the random effects model was adopted; otherwise, the fixed effects model was used. Potential publication bias was assessed using funnel plots, Egger's test, and Begg's test. 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 In this paper, according to the histological types of bone and soft tissue sarcoma, it will be divided into liposarcoma, non liposarcoma soft tissue sarcoma and osteosarcoma, and the subgroup analysis will be carriedout.

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.

Language restriction English and Chinese language.

Country(ies) involved China.

Keywords Sarcoma; Rigofinib; Meta analysis.

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