INPLASY PROTOCOL

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None declared.

Efficacy and safety of stereotactic body radiotherapy for pain relief of bone metastases: evidence from randomized controlled trials

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Review question / Objective: **We aim to conduct a systematic review and meta-analysis to compare the effects of stereotactic body radiotherapy versus conventional external radiation for pain relief based on randomized controlled trials.**
Condition being studied: **Pain relief is one of the main objectives of radiotherapy for cancer patients with bone metastases. In recent years, several trials have reported the comparison of pain relief rate between stereotactic body radiotherapy (SBRT) and conventional external beam radiation (EBR) in patients with painful bone metastasis. However, no systematic review or meta-analysis had been done till now, and the results of those investigations were inconsistent. Here we aim to perform a meta-analysis of the available randomized controlled trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 June 2022 and was last updated on 25 June 2022 (registration number INPLASY202260099).

INTRODUCTION

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METHODS

Search strategy: MEDLINE, EMBASE, the Clinical Trials.gov, and Cochrane Central Register of Controlled Trials (CENTRAL) has been systematically searched by two separate investigations to identify relevant studies published until May 1, 2022. The following keywords (in the title/abstract) were used: (Stereotactic body radiotherapy OR SBRT) AND (spinal metastases OR bone metastases).

Participant or population: Adult patients diagnosed with painful bone metastases (ie, a worst pain score at least ≥2 of 10, according to the Brief Pain Inventory (BPI)

Intervention: SBRT.

Comparator: Conventional EBRT.

Study designs to be included: Randomized controlled trial

Eligibility criteria: The following are the criteria we set: (1) study type: RCT; (2) language restriction: only available in English;(3) participants: adult patients diagnosed with painful bone metastases (ie, a worst pain score at least ≥2 of 10, according to the Brief Pain Inventory (BPI); (4) intervention: SBRT or conventional EBRT in Intent-to-Treat Population. (5) outcomes: The primary outcome was the rate of patients with pain response at 3 months. The secondary outcomes included the rate of pain responders at 1 month and 6 months, oral morphine equivalent dose (OMED) use. And safety outcome are adverse events. Included studies were not required to provide all of the aforementioned outcomes.

Information sources: MEDLINE, EMBASE, the Clinical Trials.gov, and Cochrane Central Register of Controlled Trials (CENTRAL)

Main outcome(s): The primary outcome was the rate of patients with pain response at 3 months.

Additional outcome(s): The secondary outcomes included the rate of pain responders at 1 month and 6 months, oral morphine equivalent dose (OMED) use. And safety outcome are adverse events.

Quality assessment / Risk of bias analysis: The Review Manager 5.3 software was used to examine the risk of bias plot for individual research. The Cochrane Collaboration's consistent criteria for assessing the risk of bias in RCTs were used, which included selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential biases. The bias criteria were categorized as "low," "high," or "unclear."

Strategy of data synthesis: STATA software 12.0 (STATA Corp., College Station, Texas, USA) was used to assess the data. For the dichotomous outcomes, the risk ratio (RR) with the 95% confidence interval (CI) was analyzed and calculated with a random-effects model. For all the analyses, two tailed tests were performed, and a P value of less than 0.05 was considered to be statistically significant.

Subgroup analysis: NA.

Sensitivity analysis: Heterogeneity was estimated via the I2 statistic, where a value of less than 30% suggested "low heterogeneity"; that between 30 and 50% means "moderate heterogeneity," and that of greater than 50% denotes "substantial heterogeneity." Sensitivity analysis was used to explore the stability of the consolidated results.

Language: English.

Country(ies) involved: China.

Keywords: bone metastases; conventional external radiation; stereotactic body radiotherapy; pain relief; Meta-Analysis.

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