INPLASY PROTOCOL

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

Conflicts of interest: None.

Effectiveness of intraoperative radiotherapy versus hypofractionated postmastectomy radiotherapy for early stage breast cancer: A protocol for systematic review and meta-analysis

Feng, JY[1]; Li, G[2]; Guo, Y[3]; Gao, YH[4]; Ma, SY[5].

Review question / Objective: To compare the effectiveness of intraoperative radiotherapy versus hypofractionated postmastectomy radiotherapy for early stage breast cancer.
Condition being studied: Intraoperative radiotherapy, hypofractionated postmastectomy radiotherapy, breast cancer, protocol, systematic review, meta-analysis.
Information sources: Four English databases (PubMed, Embase, Cochrane Library, and Web of Science) and three Chinese databases (China National Knowledge Infrastructure, China Science and Technology Journal Database, and Chinese Biomedical Literature Database) will be searched from inception of databases to December 2020 without language limitation. Additional trials will be searched by reviewing the reference lists of the retrieved articles, conference proceedings, and gray literature. The detailed search strategy for PubMed is shown in Table 1. The similar search strategies will be used for other electronic databases.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 November 2020 and was last updated on 26 November 2020 (registration number INPLASY2020110115).

INTRODUCTION

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METHODS

Participant or population: Participants diagnosed with early stage breast cancer will be included.

Intervention: In the treatment group, patients were given intraoperative radiotherapy.

Comparator: It the control group, patients were given hypofractionated postmastectomy radiotherapy.

Study designs to be included: RCTs comparing the effectiveness of intraoperative radiotherapy versus hypofractionated postmastectomy radiotherapy for early stage breast cancer will be included without language limitation.

Eligibility criteria: RCTS of intraoperative radiotherapy versus hypofractionated postmastectomy radiotherapy for early stage breast cancer.

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Main outcome(s): The recurrence rate and the rate of 5-year disease-free survival will be designated as the primary outcome.

Additional outcome(s): Adverse events will be designated as the secondary outcome.

Quality assessment / Risk of bias analysis: Cochrane risk of bias assessment tool will be used to assess the risk of bias of the included studies. Seven items such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias will be evaluated by two reviews independently. Any disagreement will be resolved by the third reviewer.

Strategy of data synthesis: Review Manager 5.3 (The Cochrane Collaboration, Software Update, Oxford, UK) will be used for data synthesis. Risk ratio will be used for dichotomous outcomes with 95% confidence interval. Continuous outcomes will be presented as mean difference or standardized mean difference with 95% confidence interval. We will use I2 test to identify heterogeneity. The I2 value > 50% means significant heterogeneity, and the random effects model will be used. The I2 value ≤ 50% means minor heterogeneity, and the fixed effects model will be utilized.

Subgroup analysis: Subgroup analysis will be performed based on the different participant characteristics and outcome indicators to check the potential heterogeneity and inconsistency. If significant heterogeneity still exists after subgroup analysis, meta-analysis will not be pooled, and descriptive summary will be reported.

Sensibility analysis: Sensitivity analysis will be performed to test the robustness and reliability of pooled results by eliminating studies in low quality.

Country(ies) involved: China.

Keywords: intraoperative radiotherapy, hypofractionated postmastectomy radiotherapy, breast cancer, protocol, systematic review, meta-analysis.

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