INPLASY PROTOCOL

To cite: Liang et al. Efficacy and safety evaluation of radiotherapy options after lumpectomy for early-stage breast cancer: a systematic review and network meta-analysis of randomized clinical trials. Inplasy protocol 202180093. doi: 10.37766/inplasy2021.8.0093

Received: 24 August 2021

Published: 24 August 2021

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Support: None.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None declared.

Efficacy and safety evaluation of radiotherapy options after lumpectomy for early-stage breast cancer: a systematic review and network meta-analysis of randomized clinical trials

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Review question / Objective: P: early-stage breast cancer; I: radiotherapy options after lumpectomy; C: whole-breast irradiation (WBI); O: the primary endpoint is the rate of ipsilateral breast tumor recurrence. Secondary endpoints are overall survival, disease-free survival, distant metastasis survival, acute toxicity, lateral mortality, cosmetic outcome. S: randomized clinical trials.

Condition being studied: The traditional radiotherapy after lumpectomy for early-stage breast cancer is WBI. Nowadays, ASTRO and ESTRO guidelines recommend using accelerated partial breast irradiation (APBI) instead of WBI for selected early-stage breast cancer. Options of APBI mainly include external beam radiation therapy, brachytherapy and intraoperative radiotherapy that has recently reported its long-term results. To evaluate the efficacy and safety evaluation of radiotherapy options after lumpectomy for early-stage breast cancer. We are going to conduct a systematic review and network meta-analysis of randomized clinical trials.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 August 2021 and was last updated on 24 August 2021 (registration number INPLASY202180093).

INTRODUCTION

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METHODS

Participant or population: (1) early-stage breast cancer; (2) after breast-conserving surgery; (3) receiving breast radiotherapy.

Intervention: The group receiving accelerated partial breast radiotherapy.

Comparator: The group receiving whole breast radiotherapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: (1) early-stage breast cancer; (2) breast-conserving surgery; (3) breast radiotherapy; (4) two independent comparison groups; (5) at least one endpoint was reported; (6) randomized controlled trials (RCTs); (7) language restrictions in English; (8) the sample size of the study was more than 50 cases.

Information sources: A systematical research will be performed of PubMed, EMBASE, WOS and Medline, and the Cochrane Library.

Main outcome(s): The primary endpoint is the rate of ipsilateral breast tumor recurrence.

Additional outcome(s): Secondary endpoints are overall survival, disease-free survival, distant metastasis survival, acute

toxicity, lateral mortality, cosmetic outcome.

Quality assessment / Risk of bias analysis:

The quality will be assessed as the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group. Risk of bias will be assessed the Cochrane Collaboration tool.

Strategy of data synthesis: Using the Cochrane Q test and the I2 statistics to evaluate the heterogeneity between studies. If heterogeneity is present (P50%), the statistical pooling of effect measures is based on the random-effect model. Otherwise, a fixed-effect model is employ. Forest plots with heterogeneity estimates will be generated.

Subgroup analysis: Subgroup analysis will be performed if possible.

Sensitivity analysis: The sensitivity analysis will be conducted by omitting one study in each turn.

Language: English.

Country(ies) involved: China.

Keywords: Breast cancer, Accelerated partial breast irradiation, Whole-breast irradiation, Network Meta-analysis.

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