INPLASY

Effectiveness of Trolamine in Preventing Radiotherapy-Related Skin Toxicity in Breast Cancer: A Meta-Analysis and TSA Study of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 January 2025 and was last updated on 20 January 2025.

INTRODUCTION

Review question / Objective This review aims to assess the effectiveness of trolamine in preventing radiotherapy-induced skin damage in breast cancer patients, providing solid evidence to guide its clinical use.

Condition being studied Patients with breast cancer undergoing radiotherapy, with a focus on radiotherapy-related skin toxicity, a common and impactful side effect of the treatment.

METHODS

Participant or population Female breast cancer patients receiving radiotherapy.

Intervention The use of trolamine, applied topically, to prevent or reduce the severity of skin toxicity associated with radiotherapy in breast cancer patients.

Comparator Standard care or a placebo group, which provides a comparison to the effectiveness of trolamine in reducing radiotherapy-induced skin toxicity.

Study designs to be included RCTs.

Eligibility criteria RCTs that investigated the effect of trolamine on radiotherapy-induced skin toxicity in breast cancer patients, with outcomes reported on skin toxicity levels, side effects, and quality of life.

Information sources PubMed, Embase, Cochrane Library, Web of Science, ClinicalTrials.gov, CNKI, Wanfang Data, VIP Database, and CBM.

Main outcome(s) Degree of skin toxicity (e.g., erythema, dermatitis), any adverse reactions to trolamine, and impact on the quality of life of the patients during and after radiotherapy.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias tool was used to assess the quality of the included studies. Evidence quality for each outcome was rated using the GRADE approach.

Strategy of data synthesis Meta-analysis was performed using RevMan 5.4 software. Continuous outcomes were analyzed as mean differences (MDs) with 95% confidence intervals (CIs), while dichotomous outcomes were presented as relative risks (RRs). Heterogeneity was examined using random-effects models. TSA was applied to verify the stability and validity of the findings.

Subgroup analysis Subgroup analyses explored the effectiveness of trolamine based on different levels of skin toxicity severity (e.g., mild, moderate, severe), as well as different timings of trolamine application in relation to radiotherapy.

Sensitivity analysis Sensitivity analysis was conducted by excluding individual studies to test the robustness and consistency of the results across the entiredataset.

Country(ies) involved China.

Keywords Radiotherapy; Skin Toxicity; Trolamine; Breast Cancer; Meta-analysis; Randomized Controlled Trials.

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