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Topical Calendula officinalis for the prevention of radiation dermatitis in cancer patients undergoing radiotherapy: a systematic review and meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION**Support** - No support.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202670128**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 July 2026 and was last updated on 31 July 2026.**INTRODUCTION**

Review question / Objective To evaluate the efficacy of topical Calendula officinalis preparations compared with any control for the prevention of grade ≥ 2 acute radiation dermatitis in cancer patients receiving external beam radiotherapy ($\pm$ chemotherapy/surgery).

Condition being studied Acute radiation dermatitis induced by external beam radiotherapy ($\pm$ concurrent chemotherapy) in cancer patients (breast cancer and head and neck cancer). It is an acute inflammatory skin reaction progressing from erythema through dry desquamation to moist desquamation (RTOG/CTCAE grade ≥ 2), associated with pain, burning, itching, and potential treatment interruptions.

METHODS

Participant or population Cancer patients (aged ≥ 18 years) receiving external beam radiotherapy ($\pm$ concurrent chemotherapy, $\pm$ surgery) for breast cancer or head and neck cancer

Intervention Topical Calendula officinalis preparations (ointments, creams, lotions, oils, or gels), at any concentration, frequency, or treatment duration, applied to the irradiated skin area starting from the first day of radiotherapy.

Comparator Any control (placebo, standard skin care, aqueous cream, trolamine, essential fatty acids, sorbolene, or herbal ointment). When Calendula served as the comparator arm, treatment arms were reversed so that Calendula was uniformly treated as the experimental intervention.

Study designs to be included Randomized controlled trials with parallel-group or crossover designs. Non-randomized studies, observational studies, case reports, reviews, editorials, conference abstracts without full text, protocols without results, and animal studies were excluded.

Eligibility criteria Inclusion:

1. Randomised controlled trials

2. Cancer patients receiving external beam radiotherapy ($\pm$ chemotherapy/surgery)
3. Topical *Calendula officinalis* preparations (any formulation, concentration, frequency, or treatment duration)
4. Reporting the incidence of grade ≥ 2 acute radiation dermatitis (RTOG or CTCAE) as extractable dichotomous data

Exclusion:

1. Calendula combined with other active herbal ingredients in the same arm, where the isolated effect of Calendula could not be determined.

Information sources PubMed, Embase, Web of Science, Cochrane CENTRAL, CBM, CNKI, Wanfang, VIP. Trial registries: ClinicalTrials.gov, ChiCTR.

Main outcome(s) Incidence of grade ≥ 2 acute radiation dermatitis, assessed using the RTOG acute radiation morbidity scoring criteria or CTCAE version 4.0, recorded during the radiotherapy treatment period and up to 30 days following its completion.

Quality assessment / Risk of bias analysis Risk of bias was assessed independently by two reviewers using the Cochrane Risk of Bias Tool 1.0 (seven domains). Figures were generated using RevMan 5.4.

Strategy of data synthesis A random-effects model (Mantel-Haenszel method, DerSimonian-Laird estimator) was applied using RevMan 5.4 to calculate pooled risk ratios (RR) with 95% confidence intervals. Heterogeneity was assessed with I^2 and Cochrane Q test.

Subgroup analysis Cancer type: breast cancer vs. head and neck cancer.

Sensitivity analysis

1. Sequential leave-one-out removal of individual studies
2. Exclusion of the high risk-of-bias study (Schneider 2015)
3. Fixed-effect model as an alternative to the random-effects model.

Country(ies) involved China.

Keywords Calendula officinalis; Radiation dermatitis; Radiotherapy;.

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