INPLASY

Dose and Timing in Postoperative Radiotherapy for Ear Keloids: A Systematic Review and Meta-Regression Protocol

INPLASY202680086
doi: 10.37766/inplasy2026.8.0086
Received: 23 August 2026
Published: 24 August 2026

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ADMINISTRATIVE INFORMATION

Support - No specific financial support was received for this systematic review.

Review Stage at time of this submission - Risk of bias assessment.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202680086

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 August 2026 and was last updated on 24 August 2026.

INTRODUCTION

Review question / Objective To assess recurrence after excision and postoperative radiotherapy for ear keloids, and to examine whether recurrence is associated with biologically effective dose (BED) and the timing of radiotherapy after surgery. We also plan to compare BED calculated using α/β ratios of 2 and 10 Gy, and to explore other treatment-related factors including surgical technique, radiotherapy modality, and follow-up.

Rationale Postoperative radiotherapy is widely used after excision of ear keloids, but treatment regimens vary considerably in dose, fractionation, modality, and timing. This makes it difficult to compare studies using total physical dose alone. BED may provide a more useful way to compare different fractionation schedules, although the most appropriate α/β ratio for keloids remains uncertain. The effect of treatment timing is also unclear, partly because timing is often reported together with other treatment differences. We therefore planned an ear-specific review to examine dose and timing within the same framework.

Condition being studied Ear keloids, including earlobe and other auricular keloids, treated with surgical excision followed by postoperative radiotherapy.

METHODS

Search strategy PubMed, Embase, the Cochrane Library, and Web of Science were searched from database inception to July 14, 2026. The search combined terms related to keloids, surgery or excision, and radiotherapy. Ear-related search terms were not used so that potentially eligible studies were not missed; ear-specific eligibility was assessed during screening.

Participant or population Patients with ear keloids, including earlobe and other auricular keloids, who underwent surgical excision followed by postoperative radiotherapy. Studies including

multiple anatomical sites were eligible only if ear-specific outcomes could be extracted separately.

Intervention Excision of the ear keloid followed by postoperative radiotherapy, regardless of radiotherapy modality, dose-fractionation schedule, or timing after surgery.

Comparator No single comparator was required. Comparisons were made across treatment arms according to BED, radiotherapy timing, surgical technique, and radiotherapy modality where data were available.

Study designs to be included Randomized trials, prospective or retrospective cohort studies, and case series reporting eligible ear-keloid outcomes are eligible for inclusion.

Eligibility criteria Studies were eligible if they included ear keloids treated with surgical excision followed by postoperative radiotherapy, reported extractable recurrence outcomes, had at least 12 months of follow-up, and included at least 10 lesions or patients in the analytic unit. Studies were excluded if radiotherapy was given without prior excision, if intralesional corticosteroids were routinely used before recurrence, or if ear-specific outcomes could not be separated from other anatomical sites. Studies without enough information to calculate BED could still be included in analyses that did not require BED.

Information sources PubMed, Embase, the Cochrane Library, and Web of Science.

Main outcome(s) Recurrence of ear keloids after excision and postoperative radiotherapy, using the definition reported in each study and the latest eligible follow-up of at least 12 months. Recurrence will be analysed as a proportion. Associations between recurrence and treatment-related factors, including BED and postoperative radiotherapy timing, will be examined by meta-regression.

Additional outcome(s) Adverse events and complications related to postoperative radiotherapy, including acute skin reactions, pigmentary change, wound complications, severe toxicity, chondritis, ulceration, and malignancy when reported. These outcomes will be summarized descriptively because definitions, grading and denominators may differ across studies.

Data management Search records were managed in EndNote. After duplicate removal, two reviewers independently screened titles and abstracts and then full texts. Data were extracted independently using a standardized extraction form. Disagreements were resolved by discussion, with unresolved cases referred to a third senior reviewer.

Quality assessment / Risk of bias analysis Risk of bias is being assessed using the Joanna Briggs Institute Critical Appraisal Checklist for Case Series. The two randomized trials are also being assessed using RoB 2 in their original randomized comparisons. Assessments are performed independently by two reviewers, with disagreements resolved by discussion and, if needed, by a third reviewer.

Strategy of data synthesis Overall recurrence will be pooled using a random-effects generalized linear mixed model. For treatment-arm analyses, recurrence proportions will be analysed with random-effects meta-regression. BED will be calculated using α/β ratios of 2 and 10 Gy, and the two specifications will be compared using model-fit measures. Univariable meta-regression will be used to examine candidate moderators. The primary meta-regression will include BED and reported surgery-to-radiotherapy timing together. Additional BED-adjusted models will examine surgical technique, radiotherapy modality, and reported follow-up. Heterogeneity will be assessed using τ^2 and I^2, and model fit will be compared using AICc and BIC where appropriate.

Subgroup analysis Descriptive subgroup analyses will be performed by surgical technique and radiotherapy modality when enough data are available. Surgical technique will be grouped as total/extralesional versus core/intralesional excision. Radiotherapy modality will be grouped as superficial/orthovoltage X-ray therapy, electron-beam radiotherapy, or brachytherapy. Subgroup estimates will be pooled separately and interpreted descriptively.

Sensitivity analysis Sensitivity analyses will include alternative coding rules for postoperative radiotherapy timing, multilevel models accounting for multiple treatment arms from the same study, exclusion of patient-based datasets, and GLMM-based meta-regression without continuity correction. The primary BED-plus-timing model will also be assessed using leave-one-study-out analysis.

Language restriction No language restrictions were applied during the search.

Country(ies) involved Taiwan.

Keywords keloid; ear keloid; radiotherapy; postoperative radiotherapy; biologically effective dose; recurrence; meta-analysis; meta-regression.

Dissemination plans The findings will be submitted for publication in a peer-reviewed journal.

Contributions of each author

Author 1 - Pei-Lin Wu - Study design, literature search, study selection, data extraction, risk-of-bias assessment, statistical analysis, and manuscript writing.
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Author 2 - Yi-Chuan Chan - Data extraction, data checking, manuscript writing and revision.
Author 3 - Yao-Cheng Wu - Risk-of-bias assessment, manuscript writing and revision.
Author 4 - Yung-Shuo Kao - Supervision, methodological advice, interpretation of the results, and manuscript review.