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# A Comparative Study to Evaluate the Efficacy and Safety of Intralesional Triamcinolone versus Intralesional 5-FU in Keloid Treatment

**Dr. Taijal Goyal[1], Dr. Rajkumar Kothiwala[2], Dr. Abhinav Awasthi[3], Dr. Ajay Singh[4]**

**Abstract:** ***Background: Keloids represent a challenging fibrotic skin disorder with high recurrence and significant psychosocial impact. Multiple intralesional therapies have been advocated, yet direct comparative data remain limited. Objectives: To compare the clinical efficacy and safety profiles of intralesional triamcinolone acetonide (TAC) and intralesional 5-fluorouracil (5-FU) in treating keloid scars. Methods: In a prospective, randomized study of 50 adults with keloids, participants were allocated to receive either intralesional TAC or 5-FU at two-week intervals for up to six sessions. Efficacy was assessed using the Vancouver Scar Scale (VSS), symptom scores, and objective scar measurements at baseline and follow-up. Adverse events were recorded throughout. Results: By week 12, complete scar flattening (VSS height 0) was achieved in 68% of the TAC group and 44% of the 5-FU group. Both treatments produced significant reductions in pigmentation, vascularity, pliability, and symptoms. TAC accelerated cosmetic improvement but was associated with more atrophy and telangiectasia, while 5-FU reduced scar bulk and pruritus faster but caused greater injection discomfort and occasional ulceration. Long-term recurrence data were limited due to 6-month follow-up. Conclusions: Both TAC and 5-FU are effective and safe for keloid management. TAC may produce more rapid cosmetic improvement, whereas 5-FU may be preferred for patients at risk of steroid side effects. Combination therapy and longer-term outcomes warrant future research.***

**Keywords:** Keloid, intralesional triamcinolone, intralesional 5-fluorouracil, randomised controlled trial, Vancouver Scar Scale, scar treatment, fibrotic disorders, scar flattening, dermatologic therapy

## 1. Introduction

Keloids are benign, fibroproliferative scars resulting from dysregulated wound healing, marked by persistent inflammation and excessive collagen deposition. They are more common in younger adults, especially those of darker skin phenotypes, and are associated with considerable physical and psychological morbidity due to their chronic, disfiguring nature. Current treatment strategies for keloids are diverse, but none offer consistently curative outcomes, with high rates of recurrence widely reported. Among various options, intralesional corticosteroids (notably triamcinolone acetonide) and chemotherapeutic agents like 5-fluorouracil (5-FU) are commonly used. Each exhibits distinct mechanisms and side effect profiles, but direct comparative data, especially from randomized Indian cohorts, are limited. This study was designed to evaluate and compare the effectiveness and safety of TAC and 5-FU in a randomized, controlled hospital-based setting. Taijal_Thesis_Updated. docx

## 2. Methodology

**Study Design**: Prospective, comparative, randomized controlled trial conducted from January 2024 to December 2024 in the Dermatology Department at JLN Medical College Hospital, Ajmer.

**Participants**: Fifty adult patients (age 20–50) with clinically diagnosed keloids of at least six months' duration, randomized equally into two arms (n=25 each).

**Exclusion Criteria**: Acute systemic illness, uncontrolled co-morbidities, local infection of keloids, recent keloid treatment or immunosuppressive use, pregnancy, lactation, and immunodeficiency.

**Interventions**:

- *Group A*: Intralesional triamcinolone acetonide 40 mg/mL, 0.2 mL/cm^2 lesion, max 40 mg/session, injections every 2 weeks, up to 6 sessions or until flattening.
- *Group B*: Intralesional 5-FU 50 mg/mL, 0.2 mL/cm^2, max 100 mg/session, every 2 weeks, up to 6 sessions or until flattening. Taijal_Thesis_Updated. docx

**Assessments**: All lesions were evaluated at baseline and at 2-week intervals via the Vancouver Scar Scale (subscores: pigmentation, vascularity, pliability, height), symptom analog scales, and standardized photography. Adverse events were systematically recorded.

**Data Analysis**: Statistical analysis was performed using SPSS. Continuous variables were compared using t-tests or Mann-Whitney U, categorical with chi-square. Intention-to-treat and per-protocol analyses were both conducted.

## 3. Results & Discussion

**Demographics**: Both groups were balanced in terms of age, sex, keloid site, symptom profile, family history, and keloid duration. Taijal_Thesis_Updated. docx

**Efficacy**:

- Mean total VSS scores declined steadily in both groups, with a slightly faster early response for TAC.
- Complete flattening occurred in 68% (TAC) vs.44% (5-FU), and good-to-excellent response rates (≥75% VSS improvement) were 72% (TAC) vs.64% (5-FU).
- Both arms achieved substantial reductions in scar height, pliability, pigmentation, and vascularity.5-FU was particularly notable for rapid relief in pruritus and tenderness.

**Safety**:

- Immediate injection pain was more pronounced in 5-FU (88% experienced pain) than TAC (56%).
- Late complications included skin atrophy and telangiectasia (TAC, 24%), and ulceration (5-FU, 16%). Overall, adverse event profiles were agent-specific but rates were comparable.

**Interpretation**:

- Both TAC and 5-FU demonstrated significant effectiveness for keloid scar reduction.
- TAC may be chosen when rapid flattening and improvement in colour/texture are prioritized, while 5-FU is favoured in steroid-intolerant cases and those needing faster itch relief.
- Though combination therapy is appealing and supported by referenced literature, this study did not directly assess combined modalities.
- Limitations included moderate sample size, lack of long-term recurrence tracking, and unblinded intervention. Placebo response and needling effects could not be fully excluded.

## 4. Conclusions

Intralesional triamcinolone and 5-fluorouracil both offer meaningful therapeutic benefit for keloid scars, with reasonable safety and high patient satisfaction. Triamcinolone may have a modest advantage in early flattening and vascularity improvement; 5-FU offers comparable long-term benefits with less risk of atrophy but more pain and occasional ulceration. Individual patient factors and side-effect tolerability should guide regimen selection. Combination approaches, larger studies, and longer follow-up are warranted to refine best practices for keloid management. Taijal_Thesis_Updated. docx

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