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Comparing the Efficacy of Oral Fluconazole versus Oral Itraconazole in Treating Resistant Tinea Corporis

Urooj Fatima[1*], Uzma Ali[1], Shumaila Khan[1], Danial Hassan Adil[1], Rimsha Rehman[1] and Ayesha Jamal[1]

[1]Department of Dermatology, Capital Hospital Capital Development Authority, Islamabad, Pakistan

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***Corresponding Author:**
Urooj Fatima
Department of Dermatology, Capital Hospital Capital Development Authority, Islamabad, Pakistan
urooj29scorpio@gmail.com

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ABSTRACT

Dermatophytosis, particularly tinea corporis, has become challenging due to rising antifungal resistance, notably Trichophyton indotineae. Comparative efficacy data for oral fluconazole versus itraconazole in resistant cases in local populations remain limited. **Objectives:** To compare the efficacy and safety of oral fluconazole versus oral itraconazole for resistant tinea corporis. **Methods:** This single-blind randomized controlled trial (trial reference CPSP/REU/EDR-2023-253-19306) was conducted at Capital Hospital CDA, Islamabad, from June to October 2025. 126 adults with clinically and KOH microscopy-confirmed resistant tinea corporis were randomized 1:1 to receive oral itraconazole 200 mg daily or fluconazole 150 mg every other day for 4 weeks. The primary outcome was complete clinical cure (erythema=0, scaling=0, pruritus=0, no visible lesions) at week 4. Secondary outcomes included percentage improvement in clinical signs and adverse events. **Results:** Complete clinical cure was achieved in 79.4% (50/63) with itraconazole versus 66.7% (42/63) with fluconazole (p=0.109; risk difference 12.7%, 95% CI −2.8 to 28.2). The primary endpoint did not reach statistical significance. However, mean percentage improvements were significantly higher with itraconazole for erythema (45.3% vs 36.4%; p=0.027), scaling (39.5% vs 30.2%; p=0.041), pruritus (52.6% vs 43.3%; p=0.038), and elevated borders (38.3% vs 31.6%; p=0.015). Itraconazole remained an independent predictor of cure (adjusted OR 2.12, 95% CI 1.04–4.31; p=0.037). Mild adverse effects occurred in 9.5% vs 14.3% (p=0.581). **Conclusions:** Although the difference in complete clinical cure rates (primary endpoint) was not statistically significant, itraconazole showed greater clinical improvement across secondary endpoints and was independently associated with higher odds of cure compared to fluconazole.

INTRODUCTION

Dermatophytes are the leading cause of fungal infections in the world, impacting millions of individuals each year. These are filamentous fungi that can infect keratinized tissue such as skin, hair, and nails, which are classified into three genera, Trichophyton, Epidermophyton, and Microsporum [1]. Another method is to classify dermatophytosis clinically based on site of infection from head to toe, i.e., tinea corporis, tinea capitis, tinea barbae, tinea facies, tinea manuum, tinea unguium, tinea cruris, and tinea pedis [2]. Irrespective of classification, these fungi have exhibited an increase in resistance towards various anti-fungal agents, and this problem is growing with each passing day, creating a therapeutic conundrum for treating physicians [3, 4]. Here are numerous host defensive mechanisms that prevent the spread of infection, including skin type, UV exposure, dryness, and warm temperature [5]. However, when the infection ensues, it becomes very difficult to treat in some cases due to its resistant and relapsing nature, for which numerous strategies are employed, like using various formulations and combinations of anti-fungal [6, 7]. In this instance, a study was conducted with the aim of comparing the efficacy of multiple oral anti-fungal agents for managing resistant cases of tinea infection, including the tinea

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corporis. Fluconazole and itraconazole were part of this study, and upon comparison, it was found that oral itraconazole was significantly better than oral fluconazole in terms of frequency of complete clinical resolution (72.2% versus 16.7%, respectively)[8]. Similarly, in another study, it was found that the frequency of complete clinical resolution of resistant tinea of all types of superficial dermatophytosis was much higher with itraconazole as compared to fluconazole (84% versus 62%, respectively) [9]. When it comes to previous studies regarding the efficacy of oral itraconazole and fluconazole in managing resistant tinea, studies have not focused on any specific type, and data regarding this in the local population is also lacking. Additionally, the skin type of populations is different in different geographical regions, and the pattern of anti-fungal resistance is also highly variable with changing demographics[10, 11].

Pakistan does not have quality comparative data on oral fluconazole versus itraconazole of resistant tinea corporis specifically, and most studies conducted locally involved mixed dermatophytosis types or non-resistant case. None of the previous randomized controlled trials have undergone the use of these azoles in the Pakistani population in KOH-confirmed resistant tinea corporis. This study aimed to compare the efficacy of oral fluconazole versus oral itraconazole in treating resistant tinea corporis, specifically in the local population.

METHODS

This randomized trial was carried out at the Capital Hospital's Department of Dermatology, which is governed by the Capital Development Authority (CDA) in Islamabad, Pakistan. The randomized trial was approved by the College of Physicians and Surgeons, Pakistan, CPSP, with reference number CPSP/REU/EDR-2023-253-19306, after receiving ethical approval for the study from the Institutional Research Board and Ethics Committee, Capital Hospital, CDA, under reference number IRB-89-8-2-25. The trial reference number was NCT07342153. The study was conducted from June 25, 2025, to October 1, 2025. A total of 126 patients who met the eligibility requirements were recruited from the dermatology outpatient department. Both male and female patients with clinically and mycologically verified resistant tinea corporis between the ages of 18 and 70 were included. Resistant tinea corporis was defined as persistent clinical lesions for six months or more despite adequate topical antifungal therapy, confirmed by positive 10% potassium hydroxide (KOH) microscopy demonstrating fungal hyphae from skin scrapings taken from the active border. Fungal culture and species identification were not performed owing to resource and logistical constraints in our setting. Recent (within three months) use of systemic antifungal therapy, antibiotic treatment for a superadded bacterial infection within the previous month, known immunosuppressive conditions like diabetes mellitus or cancer, immunosuppressive medication use, or azole antifungal hypersensitivity were among the exclusion criteria. Before enrollment, all individuals provided written informed consent. Following baseline evaluation, patients were randomly assigned in a 1:1 ratio to the itraconazole or fluconazole group using computer-generated random numbers via a mobile randomizer application with block randomization (block size of 4) to ensure balance. Allocation concealment was maintained using sequentially numbered opaque sealed envelopes prepared by an independent person not involved in the study. This was a single-blind randomized controlled trial in which participants were blinded to treatment allocation, while the clinical investigators were aware of group assignment due to the nature of the intervention. A 4-week treatment duration was chosen based on standard recommended regimens for systemic azoles in dermatophytosis and previous comparative trials [12-14]. Although longer courses are sometimes required in highly resistant cases, this duration allowed evaluation of standard therapy, with the option of extension outside the protocol for non-responders. Age, sex, body mass index (BMI), length of skin lesions, residence location, and educational attainment were among the baseline variables that were documented. The Dermatophyte Severity Scale (Annexure A), which rates erythema and scaling on a 4-point clinician-rated scale (0 = absent, 1 = mild, 2 = moderate, 3 = severe), and pruritus on a 0–10 patient-rated visual analog scale, was used to measure clinical severity at baseline by a consultant dermatologist. Complete clinical cure, which was defined as erythema = 0, scaling = 0, pruritus = 0, and the absence of visible lesions after 4 weeks, was the main outcome. Along with side effects, secondary outcomes were the percentage improvement in erythema, scaling, pruritus, and elevated borders compared to baseline. Outside of the trial protocol, patients who did not fully recover were given the option of extended or alternative therapy at the consultant's discretion. To minimize inter-observer variability, the same dermatologist conducted all clinical evaluations at 4 weeks. During follow-up visits, all adverse events were noted and categorized according to their severity. Considering the established safety profile of these medications, no severe side effects necessitating stopping were expected. Sample size calculation was based on expected complete clinical cure rates of 84% with itraconazole versus 62% with fluconazole from a previous study [9]. Assuming 80% power and a two-sided alpha of 0.05, the WHO sample size calculator determined that 126 patients (63 per group) were required. This gave enough power to identify group differences that were clinically

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significant. All analyses were performed on an intention-to-treat basis, including all randomized participants. The study is reported according to the CONSORT 2010 statement. The participant flow is presented in a CONSORT diagram. A CONSORT flow diagram shows flow of participants in the randomized controlled trial. Overall 126 subjects were randomly divided into two groups in the ratio of 1:1 who were to receive oral itraconazole (200mg/day) or oral fluconazole (150mg/day) as a treatment of resistant tinea corporis. Every participant in each group (n=63) received his/her treatment and did not lose follow-up or stop treatment. The two groups were examined on the basis of the intention-to-treat (ITT) principle and shown in figure 1.

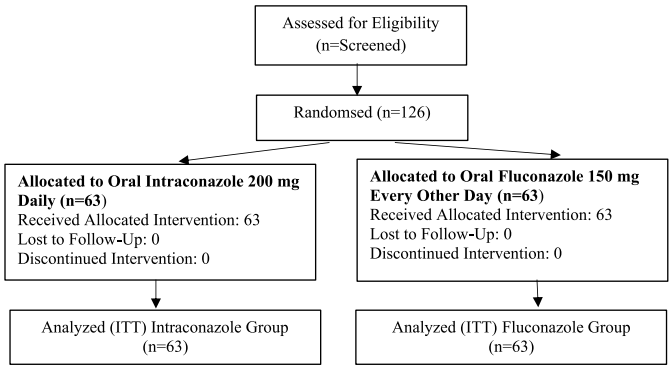

Figure 1: CONSORT flow diagram of the Randomized Controlled Trial

SPSS version 25.0 was used to analyze the data. Depending on the distribution determined by the Shapiro-Wilk test, continuous data such as age, BMI, and lesion duration were reported as mean ± standard deviation or median (interquartile range). Frequencies and percentages were used to represent categorical characteristics, including sex, residence, education, and treatment response. Primary analysis used the Chi-square test or Fisher's exact test, as applicable, to compare the percentage of patients who experienced a full clinical cure at 4 weeks between groups. Secondary analyses used independent-samples t-tests to compare mean percentage improvements in pruritus, erythema, scaling, and elevated borders. Results were stratified by age, sex, BMI, and length of lesion in subgroup analyses, and exploratory forest plots of absolute differences were produced. Using treatment group, age, sex, BMI, lesion duration, and place of residence as factors, multivariable logistic regression was used to find independent predictors of cure. For all analyses, $p<0.050$ was the threshold for statistical significance, and 95% CIs were provided.

RESULTS

Itraconazole (n=63) and fluconazole (n=63) were the two equally randomized groups into which 126 individuals with resistant tinea corporis were divided. The groups' baseline clinical and demographic traits were evenly distributed. The itraconazole group's mean age was 32.4 ± 8.7 years, while the fluconazole group was 34.9 ± 9.3 years (p=0.212). Between the two groups, the percentage of male participation was similar (55.6% vs. 52.4%; p = 0.712). BMI, lesion duration, residency area, and baseline clinical severity levels for pruritus, scaling, and erythema did not differ significantly (all p>0.050). The distribution of primary outcomes and the specific baseline parameters are shown in table 1.

Table 1: Baseline Demographic and Clinical Characteristics of Patients Receiving Itraconazole or Fluconazole and Primary Clinical Outcomes At 4 Weeks

Variables		Itraconazole, (n = 63)	Fluconazole, (n=63)	p-value
Age (years), mean ± SD		32.4 ± 8.7	34.9 ± 9.3	0.212
Male sex, n (%)		35 (55.6%)	33 (52.4%)	0.712
BMI (kg/m^2), mean ± SD		24.4 ± 3.4	24.7 ± 2.4	0.613
Lesion duration (weeks), median (IQR)		46 (39–61)	43 (38–52)	0.314
Urban residence, n (%)		35 (55.6%)	46 (73.0%)	0.054
Education ≥ primary, n (%)		38 (60.3%)	41 (65.1%)	0.571
Erythema score, median (IQR)		2 (1–3)	2 (1–3)	0.944
Scaling score, median (IQR)		2 (1–3)	2 (1–3)	0.891
Pruritus VAS, median (IQR)		6 (5–8)	6 (5–8)	0.905
Clinical Outcomes at 4 weeks	Complete clinical cure (all scores 0)	50/63 (79.4%)	42/63 (66.7%)	0.109
	Partial improvement	6/63 (9.5%)	9/63 (14.3%)	0.409
	Clinical failure	3/63 (4.8%)	7/63 (11.1%)	0.187

At 4 weeks, complete clinical cure was achieved in 79.4% (50/63) of patients in the itraconazole group versus 66.7% (42/63) in the fluconazole group (p = 0.109; risk difference 12.7%, 95% CI –2.8 to 28.2). Although the primary endpoint did not reach statistical significance, the absolute difference favored itraconazole. Lesion duration was compared using the Mann–Whitney U test as the data were non-normally distributed. Clinical failure was seen in 4.8% vs. 11.1% of patients, and partial improvement in 9.5% vs. 14.3% of patients (p>0.050 for both). After 4 weeks of treatment, both therapies produced clinically significant decreases in erythema, scaling, pruritus, and elevated borders; however, the itraconazole group's improvement was consistently larger across the board. With itraconazole, the average percentage improvement in erythema was 45.3 ± 12.4%, while with fluconazole, it was 36.4 ± 13.8% (mean difference 8.9%, 95% CI 1.2–16.6; p=0.027). The improvement in pruritus was 52.6 ± 13.1% vs. 43.3 ± 14.7% (mean difference 9.3%, 95% CI 1.5–17.1; p=0.038), and the improvement in scaling was 39.5 ± 11.2% vs. 30.2 ± 12.1% (mean difference 9.3%, 95% CI 1.1–17.5; p=0.041). Similarly, the itraconazole group's elevated borders improved by 38.3 ± 14.9%, whereas the fluconazole group's improved by 31.6 ± 36.8% (mean difference 6.7%,

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95% CI 1.5–11.9; p=0.015). Although the standard deviation in the fluconazole group was large, normality was confirmed by the Shapiro–Wilk test, and the independent-samples t-test was therefore appropriate (Figure 2).

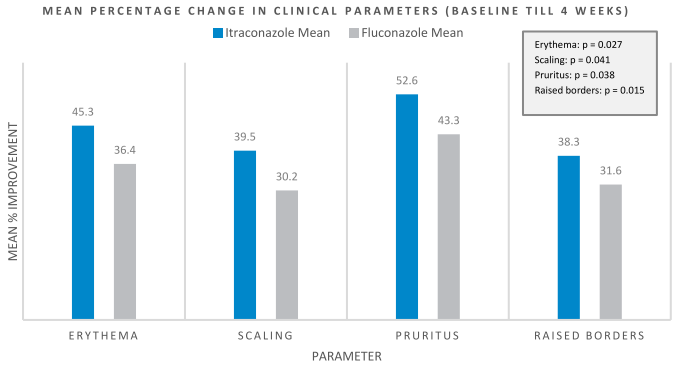

Figure 2: Mean Percentage Improvement from Baseline to Week 4 in Erythema, Scaling, Pruritus, and Raised Borders for Itraconazole and Fluconazole Groups

The two regimens were both highly received. Nine out of sixty-three patients (14.3%) receiving fluconazole and six out of sixty-three (9.5%) receiving itraconazole experienced mild adverse effects (Fisher's exact test, p=0.581). There were no significant side effects or treatment discontinuations; the most common symptoms were headache, dizziness, and gastrointestinal distress, as shown in table 2.

Table 2: Multivariable Logistic Regression Analysis for Predictors of Complete Clinical Cure at 4 Weeks

Predictor Variables	Adjusted OR	95 % CI	p-value
Itraconazole vs Fluconazole	2.12	1.04 – 4.31	0.037
Age (per year increase)	0.98	0.95 – 1.02	0.271
Male sex	1.11	0.57 – 2.16	0.759
BMI (per kg/m^2)	0.96	0.89 – 1.04	0.298
Lesion duration ≥ 1 year	0.83	0.41 – 1.69	0.614
Urban vs rural	1.27	0.64 – 2.53	0.496

The two regimens were both highly received. Nine out of sixty-three patients (14.3%) receiving fluconazole and six out of sixty-three (9.5%) receiving itraconazole experienced mild adverse effects (Fisher's exact test, p = 0.581). There were no significant side effects or treatment discontinuations, however the most common symptoms were headache, dizziness, and gastrointestinal distress.

DISCUSSION

Both oral itraconazole and fluconazole produced clinically significant improvements at four weeks in this randomized controlled study assessing resistant tinea corporis. Itraconazole, on the other hand, was independently linked to a larger chance of a full clinical cure and consistently resulted with better decreases in erythema, scaling, pruritus, and elevated borders. These results are in line with recent clinical studies that emphasize the improved pharmacokinetic characteristics of itraconazole over fluconazole, such as its longer tissue persistence, stronger keratin affinity, and wider range of activity [12, 13]. These benefits have been supported by a number of recent randomized trials, which have demonstrated that itraconazole is either clinically superior or non-inferior to other systemic antifungals, such as fluconazole, especially in cases of resistant infections [14, 15]. The complete clinical cure rates observed in the present study (79.4% with itraconazole versus 66.7% with fluconazole) align with findings from previous comparative trials, although the absolute difference was smaller than previously reported. Koregol et al. documented complete clinical resolution rates of 72.2% with itraconazole versus only 16.7% with fluconazole in resistant tinea cases [8]. Similarly, Tyagi et al. reported cure rates of 84% versus 62%, respectively, across various types of superficial dermatophytosis [9]. The narrower gap in our trial is likely attributable to our stricter inclusion criteria (clinically and mycologically confirmed resistant tinea corporis only) compared with the broader populations studied earlier. Nevertheless, the consistent direction of benefit favoring itraconazole, together with the significantly greater mean percentage improvements in erythema (45.3% vs 36.4%), scaling (39.5% vs 30.2%), pruritus (52.6% vs 43.3%), and elevated borders (38.3% vs 31.6%), further strengthens the evidence of itraconazole's superior clinical response in resistant cases. With more and more resistant infections being documented in Asia, Europe, and North America, Trichophyton indotineae's advent has altered the epidemiological landscape of dermatophytosis worldwide [16, 17]. Clinical failures are frequently linked to changes in ERG genes and other resistance mechanisms, and this pathogen is linked to decreased sensitivity to fluconazole [18-20]. The direction and consistency of the treatment effect seen in this trial, however, can be explained by the fact that itraconazole usually maintains efficacy against these resistant isolates. Serum level investigations that reveal therapeutic cut-offs connected with cure further support the pharmacologic justification for itraconazole usage in resistant tinea [21]. Clinical outcomes and medication exposure have improved due to the introduction of super-bioavailable formulations and optimized dosage regimens [22, 23]. Fluconazole, on the other hand, has demonstrated decreasing response rates over the past ten years, particularly in resistant T. indotineae infections, despite its historical effectiveness [12, 19]. Similar to results from other RCTs, subgroup analysis in this trial demonstrated a consistent itraconazole advantage across age, sex, BMI, and lesion-duration strata [14, 22]. Unlike previous comparative trials that included heterogeneous superficial dermatophytoses or non-resistant cases [8, 9], the present study specifically

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focused on clinically and mycologically confirmed resistant tinea corporis in the local Pakistani population. Multivariable modeling demonstrated itraconazole's therapeutic significance by confirming it as an independent predictor of cure, even if the absolute difference in complete cure was not statistically significant in unadjusted analysis. The global resistance epidemic must also be taken into consideration when interpreting these findings, as treatment guidelines and expert consensus statements increasingly promote itraconazole as the preferred systemic azole [16-20]. In disseminated disease, adjuvant topical treatments as luliconazole may improve results even more [24, 25].

This research has limitations. First, the follow-up was limited to a single 4-week endpoint; longer treatment and follow-up may be necessary for resistant infections and to capture recurrence data. Second, the primary outcome was clinical cure rather than mycological cure. Third, fungal culture, species identification, and antifungal susceptibility testing were not performed. Fourth, the sample size may not have been adequate for robust multivariable modeling. Fifth, the single-center design may limit generalizability. Multicenter trials with extended follow-up, mycological endpoints, and susceptibility testing are required. The future studies must concentrate on multicenter randomized trials and bigger sample sizes with longer follow-up to determine the long-term outcomes, recurrence, and long-term efficacy. Fungal culture incorporation, identification of the species (particularly Trichophyton indotineae) and antifungal susceptibility testing is suggested to provide a more accurate directive in targeted therapy. Furthermore, the future trials of combinations and dose optimization can help even more to enhance the outcomes of treatment in resistant dermatophytosis.

CONCLUSIONS

In cases of resistant tinea corporis, itraconazole showed better clinical improvement and higher adjusted odds of cure than fluconazole. These results are consistent with new worldwide data on antifungal resistance and changing therapeutic approaches.

Authors' Contribution

Conceptualization: UF
Methodology: SK
Formal analysis: UA
Writing and Drafting: DHA, RR, AJ
Review and Editing: UF, UA, SK, DHA, RR, AJ

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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