ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 09 | September - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

CLINICAL OUTCOMES OF SUPER-BIOAVAILABLE 130 MG VERSUS CONVENTIONAL 200 MG ORAL ITRACONAZOLE IN DERMATOPHYTOSIS: A RANDOMISED CONTROLLED TRIAL

Dermatology

Dr. Ankita Narola — Resident, Department Of Dermatology, Venereology And Leprology, Mahatma Gandhi Medical College And Hospital, Jaipur, Rajasthan, India

Dr. Sankalp Awasthi* — Professor & Head, Department of Dermatology, Venereology and Leprology, Geetanjali Institute of Medical Sciences, Jaipur *Corresponding Author

Dr. Rahul Kothiwala — Senior Resident, Department Of Dermatology, Venereology And Leprology, Mahatma Gandhi Medical College And Hospital, Jaipur, Rajasthan, India

Dr. Shivi Nijhawan — Associate Professor, Department Of Dermatology, Venereology And Leprology, Mahatma Gandhi Medical College And Hospital, Jaipur, Rajasthan, India

Dr. Manisha Nijhawan — HOD & Professor, Department Of Dermatology, Venereology And Leprology, Mahatma Gandhi Medical College And Hospital, Jaipur, Rajasthan, India

ABSTRACT

Background: Dermatophytosis has become increasingly recalcitrant and relapsing in India, posing therapeutic challenges. Itraconazole remains a key systemic agent, but its conventional formulation exhibits variable absorption. A super-bioavailable (SB) formulation of itraconazole has demonstrated improved pharmacokinetics, but its clinical advantage over the conventional formulation remains underexplored. **Objectives:** To compare clinical efficacy and quality-of-life outcomes of SB itraconazole 130 mg once daily versus conventional itraconazole 200 mg once daily in adults with tinea infections. **Methods:** In this hospital-based, prospective, randomised controlled trial (CTRI/2023/10/058852), 200 adults with KOH-positive tinea infection were randomised 1:1 to receive SB itraconazole 130 mg (Group A) or conventional itraconazole 200 mg (Group B) once daily for 6 weeks. Treatment response was assessed at follow-up visits scheduled at 3 weeks, 6 weeks, and a final follow-up at 12 weeks. **Results:** At baseline, both groups had comparable disease burden (mean composite scores: Group A 12.5 ± 4.0 vs Group B 13.0 ± 4.1, $p > 0.05$). By Week 3, Group A showed significantly greater clinical improvement (mean score 4.20 vs 6.68, $p = 0.001$). At Week 6, Group A maintained superiority (mean score 2.44 vs 3.38, $p = 0.001$) and achieved higher DLQI normalisation rates (83% vs 75%). By Week 12, both groups maintained low disease burden, with no statistically significant difference in composite scores ($p = 0.10$). **Conclusion:** Super-bioavailable itraconazole 130 mg once daily demonstrated faster clinical clearance and superior quality-of-life improvement compared to conventional itraconazole 200 mg. It represents a promising therapeutic advancement for effective management of dermatophytosis.

KEYWORDS

Dermatophytosis, itraconazole, super-bioavailable, DLQI, randomised controlled trial

INTRODUCTION

Dermatophytosis has emerged as a major public-health challenge across tropical regions, especially in India, where point-prevalence surveys now document community infection rates as high as 36 % and clinic-based series routinely report chronic, extensive disease[1–3]. Several inter-related factors drive this surge: widespread over-the-counter steroid–antifungal–antibacterial combinations, incomplete treatment courses, and the documented rise of terbinafine- and azole-resistant Trichophyton species[4–6]. As a result, clinicians frequently encounter cases that respond slowly—or not at all—to standard systemic therapy.

Itraconazole remains the cornerstone oral agent for tinea corporis/cruris because of its broad antifungal spectrum and fungicidal tissue concentrations[7]. Conventional pellets, however, exhibit variable dissolution that depends on gastric pH and food intake, translating into erratic bioavailability and therapeutic failures even when isolates remain susceptible in vitro[8]. To overcome these limitations, a super-bioavailable (SB) formulation (130 mg capsule) employs a solid-dispersion technology that delivers about 1.7-1.8-fold higher and less variable plasma exposure than the conventional 200 mg capsule under fasting conditions, while permitting once-daily dosing[9-10]. Early single-arm and observational studies suggest SB itraconazole achieves more rapid clinical clearance, but robust head-to-head randomized evidence is scarce[11-12].

Quality of life (QoL) impairment further underscores the need for quicker, more reliable cures. Pruritus, visible lesions and treatment fatigue significantly disrupt daily activities and DLQI scores exceeding 10 are common among Indian patients with extensive dermatophytosis[13]. A formulation that combines pharmacokinetic efficiency with convenient dosing could, therefore, shorten symptomatic periods and accelerate QoL recovery.

Aim

To compare and study the effects of oral itraconazole Super-Bioavailable 130 mg and conventional 200 mg in Tinea infection.

Objectives:

1. To compare the treatment response of oral Itraconazole 130 mg super bioavailable and 200 mg conventional.
2. To assess the effect on Quality of life with the treatment.

MATERIALS AND METHODS

This open-label, randomised trial was carried out in the Dermatology, Venereology and Leprology department of Mahatma Gandhi Medical College & Hospital, Jaipur, over 18 months.

Inclusion Criteria

1. Patients aged over 18 years with KOH-positive scraping tinea infection and involvement of more than 5% of body surface area.
2. Patients who provided written informed consent.

Exclusion Criteria

1. Patients with known renal, hepatic or cardiac diseases.
2. Pregnant or lactating women.
3. Patients with Onychomycosis.
4. Patients with history of systemic or topical (antifungal /steroid) therapy in the preceding 4 weeks.

Participants were randomized using a computer-generated list to one of two regimens: Itraconazole 130 mg SB (Group A) or Itraconazole 200 mg conventional (Group B), each taken once daily for six weeks with topical 0.25% Amorolfine cream in both the groups.

Clinical Evaluation

At baseline, week 3, week 6 and week 12, target lesion was evaluated for two symptoms (pruritus and burning sensation) and six clinical signs (erythema, scaling, vesiculation, fissuring, maceration, and exudation). Each symptom and sign were rated on a scale of 0 (none), 1 (mild), 2 (moderate) or 3 (severe) with a maximum possible total score of 24 (8 clinical features × 3). DLQI was recorded at baseline and week 6.

Statistical Analysis

The change in composite score served as the primary outcome; DLQI normalization comprised secondary outcomes. Data were analyzed with repeated-measures ANOVA (Greenhouse–Geisser correction). A two-tailed $p < 0.05$ indicated significance.

RESULTS

At Baseline (Week 0)

At enrollment, the 200 adults randomized equally to SB-itraconazole (Group A) or conventional itraconazole (Group B) were well matched across demographic and clinical variables. Approximately 60 % were men and 40 % women, with a mean age of 34 ± 11 years (range 19–58). Just over half (≈ 55 %) resided in rural or semi-urban area. Nearly half (47 %) earned their livelihood through manual or semi-skilled work, 28 % were in the service sector, and the rest were students or engaged in other occupations; two-thirds were married. Baseline disease burden was comparable, with mean composite severity scores of 12.5 ± 4.0 in Group A and 13.0 ± 4.1 in Group B, and no significant differences in the grade distribution of any of the eight clinical parameters or in DLQI strata (all $p > 0.05$). This balanced profile supports attributing subsequent outcome differences to treatment effects.

Baseline Demographic And Clinical Characteristics (n = 200)

Table 1: Baseline Demographic And Clinical Characteristics (n = 200)

Characteristic	Value
Sex	Male — 60% | Female — 40%
Age	Mean 34±11y (19–58)
Residence	Rural/semi-urban — 55% | Urban — 45%
Occupation	Manual/semi-skilled 47% | Service 28% | Students/others 25%
Marital status	Married — 65% | Unmarried — 35%
Baseline composite severity score	Group A 12.5±4.0 | Group B 13.0±4.1 (p>0.05)

Total Clinical Score Across All Weeks

At Week 3

At the interim assessment (day 21), the super-bioavailable itraconazole arm (Group A) showed markedly greater clinical resolution than the conventional-capsule arm (Group B). The mean eight-parameter composite score fell by 66 % in Group A—dropping from 12.5 to 4.20 ± 1.50—compared with a 49 % reduction in Group B from 13.0 to 6.68 ± 2.00 ($p = 0.001$).

The lower standard deviation (1.5 vs 2.0) and lower maximum score (6 vs 9) in Group A indicate that improvement with the SB formulation was not only faster but also more consistent across patients. Collectively, these findings demonstrate that super-bioavailable itraconazole delivers significantly earlier and broader symptomatic relief than the conventional 200 mg capsule by the third week of therapy.

At Week 6

By the end of the 6-week treatment course, Group A (Super-Bioavailable Itraconazole 130 mg OD) showed better clinical improvement compared to Group B. Most patients in Group A had near-complete resolution of symptoms: Over 80% had only minimal signs—such as a faint rim of erythema or mild scaling—and many had post-inflammatory hyperpigmentation and no visible lesions at all. More than 95% showed healthy, intact skin without any vesiculation, maceration, or fissuring. Exudation was absent in 86% of cases. Troublesome symptoms were largely resolved: only 7% still reported Grade 2 pruritus, and 5% reported burning sensation.

In contrast, Group B (Conventional Itraconazole 200 mg OD) showed ongoing improvement but still lagged behind Group A: Over one-third of patients in Group B still had moderate-to-severe erythema or scaling (Grades 2–3). Around 19% continued to experience moderate-to-severe itching. Markers of skin barrier damage—such as maceration, fissuring or exudation—were still present in roughly 10% of cases.

These Differences Were Reflected In The Mean Composite Symptom Score (Based On Eight Clinical Signs And Symptoms):

Group A: 2.44 ± 3.30
Group B: 3.38 ± 5.23 ($p = 0.001$, statistically significant)

Additionally, Group A had a tighter data spread, with a lower standard deviation and a lower maximum score (16 vs 21)—indicating a more uniform and complete recovery across patients in this arm.

Quality-of-life Impact At Week 6

Dermatology Life Quality Index scores corroborated the clinical findings. By treatment completion, 83 % of patients receiving SB itraconazole (Group A) had DLQI ≤ 1—essentially no impact on daily living—compared with 75 % of those on the conventional capsule (Group B). Mild residual impairment (DLQI 2–5) persisted in only 10 % of Group A versus 13 % of Group B while moderate effect (DLQI 6–10) was halved (5 % vs 8 %). Notably, higher-burden categories (DLQI 11–20) were rare in both arms but it was less common with supra-bioavailable (2%) vs conventional therapy (4%). No participant in either group fell into the "extremely large effect" bracket (DLQI 21–30).

These data show that the faster, more complete clinical clearing achieved with the super-bioavailable formulation translated directly into superior quality-of-life recovery, leaving 80 % patients essentially symptom-free in their daily activities by week 6, compared with 75% on conventional itraconazole.

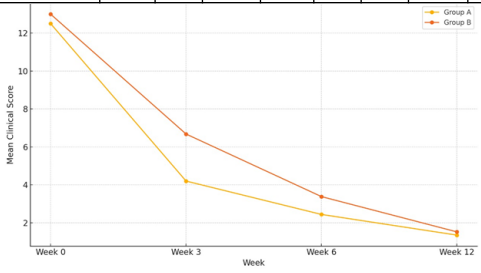
At Week 12

At the six-week post-treatment follow-up (Week 12), the vast majority of participants in both arms maintained minimal disease activity. Grade-0 scores predominated for most clinical parameters, with only small residual differences between the two formulations.

The composite clinical score reflected low overall disease burden in both treatment arms. The mean composite score was 1.35 (standard deviation [SD] = 2.320) in Group A and 1.52 (SD = 2.918) in Group B, with no statistically significant difference between the two groups ($p = 0.10$). Scores ranged from 0 to 7 in Group A and from 0 to 13 in Group B.

Table 2: Total Clinical Score across all weeks

Measure	Group A				Group B			
	Week 0	Week 3	Week 6	Week 12	Week 0	Week 3	Week 6	Week 12
Mean	12.5	4.20	2.44	1.35	13.0	6.68	3.38	1.52
Std. Deviation	4.0	1.5	3.304	2.320	4.1	2.0	5.226	2.918
Minimum score	2	2	0	0	2	3	0	0
Maximum score	18	6	16	7	19	9	21	13



Graph 1: Total clinical score across all weeks

DISCUSSION

This prospective, randomized controlled trial evaluated the comparative efficacy of super bioavailable (SB) itraconazole 130 mg once daily versus conventional itraconazole 200 mg once daily in treating extensive dermatophytosis over six weeks.

Superior Early Clinical Response With SB Itraconazole

The results demonstrated that SB itraconazole led to significantly faster and greater reductions in composite clinical severity scores by Week 3 compared to the conventional formulation. This trend was sustained through Week 6, confirming earlier reports that enhanced bioavailability translates into improved early symptom control [8,9,14]. The pharmacokinetic advantage of the SB formulation—delivering approximately 173% higher plasma exposure than the conventional capsule under fasting conditions—likely contributed to this superior performance [9,10].

These findings align with those of Narang et al[8] and Grover et al[9], who reported faster clinical clearance with SB itraconazole in recalcitrant and widespread tinea infections. The rapid reduction in erythema, scaling, vesiculation and pruritus observed in our cohort supports the hypothesis that higher and more consistent tissue concentrations of

itraconazole lead to better antifungal activity.

DLQI Normalization: A Patient-Centered Outcome

A clinically meaningful improvement in quality of life was observed in both treatment arms; however, the SB itraconazole group showed significantly higher rates of DLQI normalization (≤1) at Week 6 (83% vs 75%). This underscores the importance of early symptom relief not only from a medical standpoint but also in terms of patient-reported outcomes. Similar improvements in DLQI have been documented in other studies evaluating systemic antifungals for chronic dermatophytosis[10,13].

Given the psychosocial burden of persistent fungal infection—especially in tropical regions like India—interventions that accelerate return to normal functioning are crucial. Our findings support the inclusion of validated tools like DLQI in future trials to better capture the holistic impact of therapy.

Low Relapse Rates and Sustained Efficacy Post-Treatment

After six weeks of completion of therapy at Week 12, both groups maintained low disease burden, with minimal clinical activity. While the difference in composite scores was no longer statistically significant, the trend still favored the SB group. These results suggest that both formulations provide durable responses when administered for six weeks, although SB itraconazole offers a more robust initial response.

Importantly, relapse rates remained low in both arms, reinforcing the adequacy of a six-week course for managing extensive dermatophytosis. However, given the increasing prevalence of resistant isolates [4-6], optimizing duration and dosing remains critical. Studies such as Khurana et al [17] and Shenoy et al [18] similarly found that extended or intensified regimens may be necessary for certain subpopulations.

Comparison With Existing Literature

Our findings add to the growing body of evidence suggesting that SB itraconazole can achieve better clinical outcomes at lower doses due to its enhanced absorption and reduced inter-individual variability[9,14,16]. Compared to older formulations, supra bioavailable formulation of itraconazole gives an upper hand, especially in growing era of resistance in organism, due to its better availability and action.

Moreover, the present data align with recent meta-analyses and pharmacokinetic studies that emphasize the importance of drug delivery systems in improving antifungal efficacy[13,14]. By reducing the time to clinical response and enhancing patient satisfaction, SB itraconazole may offer an important therapeutic option in the evolving landscape of dermatophytosis management.

CONCLUSION

Once-daily SB itraconazole 130 mg demonstrated superior early clinical improvement and higher rates of DLQI normalization compared to conventional itraconazole 200 mg in the treatment of extensive dermatophytosis. Both formulations were safe and effective, with low relapse rates at six weeks post-treatment. This study provides head-to-head randomized evidence supporting the pharmacokinetic advantage of SB itraconazole, translating into earlier and more consistent clinical clearance. By including DLQI normalization as a key outcome, it underscores the patient-centered benefits of faster clearance—something underrepresented in prior trials.

Limitations

- Susceptibility testing of drugs for specific fungal agents was not performed, which may require further studies.
- The effect of drugs on different sites of infection was not compared, potentially masking variations in treatment outcomes.
- The adverse effects of the drugs were not investigated.
- Mycological culture confirmation at cure was not performed.

Conflict Of Interest: None

REFERENCES:

1. Bhatia A, Kanish B, Badyal DK, Kate P, Choudhary S. Efficacy of oral terbinafine versus itraconazole in dermatophytic skin infection: a prospective, randomised comparative study. Indian J Pharmacol. 2019;51(2):116-121.
2. Shakya NB, Jha SM, Dangol A, Shakya S, Shah A. Itraconazole versus terbinafine for tinea cruris: a comparative study. Med J Shree Birendra Hosp. 2013;11(1):24-26.
3. Majid I, Sheikh G, Kanth F, Hakak R. Relapse after oral terbinafine therapy in dermatophytosis: a clinical-mycological study. Indian J Dermatol. 2016;61(5):529-533.
4. Singh SK, Subba N, Tilak R. Efficacy of differing doses of terbinafine and itraconazole in tinea infection: an open-label RCT. Indian J Dermatol. 2020;65:284-289.
5. Shah B, et al. Comparative efficacy and safety of terbinafine and itraconazole in tinea corporis et cruris. IP Indian J Clin Exp Dermatol. 2020;6(3):231-236.
6. George M, et al. Terbinafine versus itraconazole in tinea cruris: a comparative evaluation. Int J Basic Clin Pharmacol. 2019;8(7):1460-1466.
7. Sahoo AK, Mahajan R. Management of tinea corporis, tinea cruris and tinea pedis: a comprehensive review. Indian Dermatol Online J. 2016;7(2):77-86.
8. Narang T, Kaur S, Arora P, et al. Super-bioavailable itraconazole in recalcitrant dermatophytosis: a multicentre prospective study. Mycoses. 2023;66(4):367-374.
9. Grover C, Rao R. Comparative study of conventional versus super-bioavailable itraconazole in tinea corporis/cruris. J Cutan Med Surg. 2022;26(1):53-59.
10. Agarwal R, Singh A, Yadav P, et al. Impact of oral itraconazole on quality of life in patients with chronic tinea. Dermatol Ther. 2019;32(5):e12987.
11. Gupta AK, Cooper EA. Itraconazole safety profile: a pharmacovigilance analysis of systemic antifungal therapy. Clin Drug Investig. 2021;41(10):883-893.
12. Rengasamy S, Thong-Kham D, Boonsiri T, et al. Randomised comparison of super-bioavailable versus conventional itraconazole for tinea corporis: interim results from Thailand. Dermatol Int. 2021;9(2):45-52.
13. Pan J, Zhou H, Li X, Miao Y. Efficacy of enhanced-bioavailability itraconazole formulations in cutaneous mycoses: a systematic review and meta-analysis. Mycopathologia. 2020;185(4):679-691.
14. Dhoot D, Jain GK, Manjhi M, Kesharwani P, Mahadkar N, Barkate H. Pharmacokinetic and clinical comparison of super-bioavailable itraconazole and conventional itraconazole at different dosing in dermatophytosis. Drugs Context. 2023;12:2022-8-1. doi:10.7573/dic.2022-8-1
15. Mahajan H, Dhoot D, Deshmukh G, Barkate H. Comparative clinical effectiveness and safety of super-bioavailable itraconazole and conventional itraconazole in management of dermatophytosis: a retrospective data analysis. Int J Res Dermatol. 2021;7(3):388-394.
16. Shenoy M, Dhoot D, Mahajan H, Barkate H. An open-label, randomized, double-arm clinical trial to compare the effectiveness and safety of super-bioavailable itraconazole capsules and itraconazole capsules in the management of dermatophytosis in India. Clin Cosmet Investig Dermatol. 2021;14:1367-1376. doi:10.2147/CCID.S326642
17. Khurana A, Agarwal A, Agrawal D, et al. Effect of different itraconazole dosing regimens on cure rates, treatment duration, safety, and relapse rates in adult patients with tinea corporis/cruris: a randomized clinical trial. JAMA Dermatol. 2022;158(11):1269-1278. doi:10.1001/jamadermatol.2022.3745
18. Shenoy MM, De A, Shah B, Das A, Saraswat A, Lahiri K, et al. Efficacy of super-bioavailable itraconazole and conventional itraconazole at different dosing regimens in glabrous tinea infection: a randomized clinical trial. Drug Des Devel Ther. 2023;17:2899-2908. doi:10.2147/DDDT.S421583