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Original Research Article

# A comparative study on efficacy of oral ultramicrosized griseofulvin and oral itraconazole on dermatophytic infection of skin

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## Abstract

**Introduction:** Dermatophytosis is a common superficial fungal infection affecting keratinized tissues, with significant health and cosmetic impacts. Though itraconazole is widely used due to its broad-spectrum antifungal efficacy, its higher cost and adverse effects necessitate exploration of alternatives like ultramicrosized griseofulvin. This study aimed to compare the clinical efficacy, safety, and cost-effectiveness of oral itraconazole and oral ultramicrosized griseofulvin in the treatment of tinea corporis and tinea cruris.

**Materials and Methods:** A randomized controlled trial was conducted over 24 months at Era's Lucknow Medical College & Hospital. A total of 243 patients with KOH-confirmed tinea corporis or tinea cruris were randomly allocated into two groups: Group A (n=121) received oral itraconazole 100 mg twice daily, and Group B (n=122) received oral ultramicrosized griseofulvin 500 mg twice daily for six weeks. Clinical, mycological, and symptomatic evaluations were performed at baseline and at 2, 4, 6, and 8 weeks. p-values <0.05 considered statistically significant.

**Results:** Both groups were comparable in baseline demographic and clinical characteristics. Among the 88 patients receiving itraconazole and 83 receiving ultramicrosized griseofulvin, recurrence rates were comparable. At 8 weeks, scaling resolution was significantly higher with Itraconazole (97.0% vs 76.9%), while erythema and pruritus showed similar improvement across groups. Recurrence rates and KOH negativity were comparable between groups. No adverse events necessitating treatment withdrawal were reported in either group.

**Conclusion:** Ultramicrosized griseofulvin is a safe, cost-effective, and clinically effective alternative to itraconazole for treating dermatophytosis, particularly in low-resource settings.

**Keywords:** Dermatophytosis, Itraconazole, Griseofulvin

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## 1. Introduction

Dermatophytosis is a type of superficial skin infection caused by a group of filamentous fungi called dermatophytes that affects the keratinized tissues.[1] In common parlance, they are also termed as Tinea infections.[2] These infections bring about cutaneous changes in the skin transforming into ring shaped lesions having a clear center and inflammatory edge and are therefore also termed ringworm.[3,4] Though superficial form is more abundant[5] yet they could be deeper ones affecting the stratum corneum of the epidermis, nails and hair.[6] Dermatophytosis is reported to affect nearly 20-25% of the global population.[7,8] Hospital-based studies from India report its prevalence to range from 15 to 35%.[9,10] Climatic and weather conditions in tropical countries, particularly humid environment, high temperature and sweating are conducive to growth and progression of dermatophytes.[11]

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The common dermatophyte fungi are *Epidermophyton spp., Microsporum spp.* and *Trichophyton spp.* respectively. Global and Indian epidemiological studies during the last fifty years have shown more than 70 to 80% of dermatophyte infections to be caused by *T. rubrum* only.[9,10,12,13]

Dermatophyte infections generally occur at the visible parts of body, thus affecting the appearance of an individual. The disease is not only characterized by reddish skin rashes and scaling, that are itchy but it also causes irritation, pain and cosmetic concerns among the affected patients leading to a substantial fall in quality of life.[14,15] The burden of disease is often enhanced by the development of secondary complications like bacterial infection, tinea incognito, Majocchi's granuloma, and disseminated/generalized eczema.[16]

Antifungals are the mainstay of the medical management strategy of dermatophytes. They can be used either through topical or oral routes. Itraconazole, a broad-spectrum antifungal belonging to triazole class is quite popular for treatment of various types of fungal infections. It acts by inhibiting the fungal cytochrome P-450 dependent enzyme lanosterol 14-α- demethylase that is required for maintenance of the cell membrane in the fungi and thus slows down the growth of fungi.[17,18] The efficacy of Itraconazole against fungal infections like dermatophytes, candida and some specific nondermatophytic molds is well-established.[19] In spite of the well-established efficacy profile, Itraconazole is often criticized for its some adverse effects resulting in cardiotoxicity.[20]

Griseofulvin ($C_{17}H_{17}ClO_6$), an antifungal that was first discovered in the year 1939 as a natural product derived from *Penicillium griseofulvum*, is a polyketide metabolite that was subsequently derived from a number of other fungi under the phylum ascomycetes. *Xylaria flabelliformis, Abieticola koreana, and Stachybotrys levispora* are some of the other members of phylum ascomycetes that have been recognized as the source for Griseofulvin. Compared to Itraconazole that is recognized as a broad-spectrum antifungal, Griseofulvin is effective against some specific fungi like *Trichophyton, Microsporum, and Epidermophyton* species. It acts by inhibiting the microtubule assembly caused by its interaction with microtubules leading to the formation of the mitotic spindle. As a result of this mechanism of action, griseofulvin effectively inhibits mitosis in dermatophytes. Owing to this specific mechanism of action, griseofulvin falls under the category of a fungistatic agent.[21] It is used as an oral medication that is available in microsize and ultra micro-size forms. Ultra micro-sized tablets are preferred over microsized tablets as they are absorbed better.

Over the years, comparative studies evaluating the efficacy of Itraconazole and Griseofulvin have found Itraconazole to be more effective than Griseofulvin in terms of better cure rate and lower relapse rate[22,23] though some studies found them comparable too[24] and some others have found them as a suitable alternative to itraconazole.[25] In view of shifting of focus from just the cure rate to safety and adverse effects too, the present study was planned to compare the clinical efficacy of oral Itraconazole and Ultramicrosized Griseofulvin in treatment of tinea corporis and cruris.

## 2. Materials and Methods

The randomized controlled trial was conducted over a period of 24 months at the Department of Dermatology, Era's Lucknow Medical College & Hospital, a tertiary care centre primarily catering to socio-economically underprivileged populations in Lucknow. A total of 243 freshly diagnosed cases of Tinea corporis and Tinea cruris, confirmed by potassium hydroxide (KOH) examination, were recruited from the outpatient department after obtaining informed consent. Patients aged 18 years and above were included, while those with recent antifungal treatment (within 3 months), pre-existing renal, hepatic, or cardiac disease, pregnant or lactating women, and women on oral contraceptive pills were excluded. Ethical clearance was obtained from the Institutional Ethical Committee prior to the initiation of the study.

The sample size was calculated at 120 patients per group, accounting for a 95% confidence level, 90% study power, and a 10% anticipated loss to follow-up, resulting in a total enrolment of 243 patients.[26] Patients were randomly allocated using a Sequentially Numbered Opaque Sealed Envelope (SNOSE) technique into two groups: Group A (n=121) received oral Itraconazole 100 mg twice daily, while Group B (n=122) received oral Ultramicrosize Griseofulvin 500 mg twice daily. Treatment continued until lesion resolution or for a maximum of 6 weeks, with a final follow-up at 8 weeks to assess relapse. Clinical, microbiological, and photographic documentation was performed at baseline and at 2, 4, 6, and 8 weeks. Clinical responses in terms of scaling, erythema, and pruritus were graded on a 0-3 scale, and overall response was categorized as marked improvement, considerable residual lesions, no change, or worsening. Patients achieving complete clinical resolution with negative KOH were considered cured.

Data were compiled and statistically analysed using SPSS Version 21.0. Results were expressed as numbers (percentage) and mean ± standard deviation (SD). Chi-square test and Student's t-test were used for categorical and continuous data respectively, while non-parametric data were assessed using the Mann-Whitney U test. A p-value of less than 0.05 was considered statistically significant.

## 3. Results

A total of 243 patients were enrolled—121 (49.8%) in Group A (Itraconazole) and 122 (50.2%) in Group B (Ultramicrosized Griseofulvin). The overall mean age was 33.61±13.15 years, with no significant difference between Group A (34.09±13.63) and Group B (33.13±12.69)

(p=0.570). Gender distribution was similar (p=0.140), with slightly more males in Group A (52.1%) and more females in Group B (57.4%). Occupation and diagnosis types were also comparable (p=0.244 and p=0.085, respectively).

At baseline, both groups had similar levels of moderate to severe erythema, scaling, and pruritus. By week 2, Group A showed better outcomes: more patients had no scaling (15.7% vs. 9.8%) and mild scaling (73.6% vs. 69.7%), with moderate scaling more frequent in Group B (20.5% vs. 10.7%) (p<0.05). Pruritus was also less in Group A, with more patients showing no pruritus (17.4% vs. 2.5%) and fewer with moderate severity (25.6% vs. 38.5%) (p<0.05). Erythema improvement did not differ significantly.

At week 4, severe symptoms were absent. Group A had better, though not statistically significant, erythema resolution (22.3% vs. 19.7%, p=0.088). Scaling resolution was higher in Group A (82.6% vs. 57.4%, p<0.001), and more patients had complete pruritus relief (19.0% vs. 3.3%, p=0.015).

At week 6, full resolution of scaling remained superior in Group A (95.0% vs. 86.1%, p=0.017). Improvements in erythema and pruritus were similar (p=0.157, p=0.489). KOH negativity was slightly better in Group A (73.6% vs. 68.9%, p=0.418).

At 8 weeks, the resolution rates of erythema, scaling, and pruritus in the Itraconazole group were 69.7%, 97.0%, and 81.8%, respectively, compared to 66.7%, 76.9%, and 74.4% in the Griseofulvin group. The resolution of scaling was significantly higher with Itraconazole compared to ultramicrosized Griseofulvin at 8 weeks.

**Table 1:** Comparison of Demographic and Clinical Profile of patients at enrolment

| Characteristics | Total (N=243) | Group A (n=121) | | Group B (n=122) | | Statistical significance | |
|---|---|---|---|---|---|---|---|
| **Mean age±SD (Range) in years** | 33.61± 13.15 | 34.09±13.63 (18-85) | | 33.13±12.69 (18-74) | | 't'=0.568; p=0.570 | |
| | | **No.** | **%** | **No.** | **%** | **$\chi^2$** | **'p'** |
| **Sex** | | | | | | | |
| Male | 115 | 63 | 52.1 | 52 | 42.6 | 2.173 | 0.140 |
| Female | 128 | 58 | 47.9 | 70 | 57.4 | | |
| **Occupation** | | | | | | | |
| Unskilled worker/ Farmer | 48 | 19 | 15.7 | 29 | 23.8 | 6.696 | 0.244 |
| Skilled worker/ Vendor | 30 | 19 | 15.7 | 11 | 9.0 | | |
| Clerk/Shopkeeper/ Teacher | 47 | 20 | 16.5 | 27 | 22.1 | | |
| Officer/ Professional | 11 | 6 | 5.0 | 5 | 4.1 | | |
| Homemaker | 59 | 29 | 24.0 | 30 | 24.6 | | |
| Student | 48 | 28 | 23.1 | 20 | 16.4 | | |
| **Diagnosis** | | | | | | | |
| Tinea corporis | 26 | 10 | 8.3 | 16 | 13.1 | 3.394 | 0.183 |
| Tinea cruris | 41 | 17 | 14.0 | 24 | 19.7 | | |
| Tinea cruris and corporis | 176 | 94 | 77.7 | 82 | 67.2 | | |

**Table 2:** Clinical Profile of patients in two groups at baseline and follow-ups

| Sign | No | | Mild | | Moderate | | Severe | |
|---|---|---|---|---|---|---|---|---|
| | **No.** | **%** | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| **Baseline** | | | | | | | | |
| **Erythema** | | | | | | | | |
| **Group A** | 0 | 0 | 3 | 2.5 | 33 | 27.3 | 85 | 70.2 |
| **Group B** | 0 | 0 | 6 | 4.9 | 33 | 27 | 83 | 68 |
| **z=0.482; p=0.630** | | | | | | | | |
| **Scaling** | | | | | | | | |
| **Group A** | 0 | 0 | 21 | 17.4 | 92 | 76 | 8 | 6.6 |
| **Group B** | 0 | 0 | 17 | 13.9 | 91 | 74.6 | 14 | 11.5 |
| **z=1.289; p=0.197** | | | | | | | | |
| **Pruritus** | | | | | | | | |
| **Group A** | 0 | 0 | 6 | 5 | 115 | 95 | 0 | 0 |
| **Group B** | 0 | 0 | 3 | 2.5 | 118 | 96.7 | 1 | 0.8 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **z=1.284; p=0.199** | | | | | | | | |
| **At first follow up (2 weeks)** | | | | | | | | |
| **Erythema** | | | | | | | | |
| **Group A** | 3 | 2.5 | 37 | 30.6 | 74 | 61.2 | 7 | 5.8 |
| **Group B** | 2 | 1.6 | 32 | 26.2 | 79 | 64.8 | 9 | 7.4 |
| **z=0.964; p=0.335** | | | | | | | | |
| **Scaling** | | | | | | | | |
| **Group A** | 19 | 15.7 | 89 | 73.6 | 13 | 10.7 | 0 | 0 |
| **Group B** | 12 | 9.8 | 85 | 69.7 | 25 | 20.5 | 0 | 0 |
| **z=2.289; p=0.022** | | | | | | | | |
| **Pruritus** | | | | | | | | |
| **Group A** | 21 | 17.4 | 69 | 57 | 31 | 25.6 | 0 | 0 |
| **Group B** | 3 | 2.5 | 72 | 59 | 47 | 38.5 | 0 | 0 |
| **z=3.337; p=0.001** | | | | | | | | |
| **At second follow up (4 weeks)** | | | | | | | | |
| **Erythema** | | | | | | | | |
| **Group A** | 27 | 22.3 | 84 | 69.4 | 10 | 8.3 | 0 | 0 |
| **Group B** | 24 | 19.7 | 75 | 61.5 | 23 | 18.9 | 0 | 0 |
| **z=1.705; p=0.088** | | | | | | | | |
| **Scaling** | | | | | | | | |
| **Group A** | 100 | 82.6 | 19 | 15.7 | 2 | 1.7 | 0 | 0 |
| **Group B** | 70 | 57.4 | 51 | 41.8 | 1 | 0.8 | 0 | 0 |
| **z=4.181; p<0.001** | | | | | | | | |
| **Pruritus** | | | | | | | | |
| **Group A** | 23 | 19 | 61 | 50.4 | 37 | 30.6 | 0 | 0 |
| **Group B** | 4 | 3.3 | 73 | 59.8 | 45 | 36.9 | 0 | 0 |
| **z=2.425; p=0.015** | | | | | | | | |
| **At third follow up (6 weeks)** | | | | | | | | |
| **Erythema** | | | | | | | | |
| **Group A** | 94 | 77.7 | 27 | 22.3 | 0 | 0 | 0 | 0 |
| **Group B** | 85 | 69.7 | 37 | 30.3 | 0 | 0 | 0 | 0 |
| **z=1.415; p=0.157** | | | | | | | | |
| **Scaling** | | | | | | | | |
| **Group A** | 115 | 95 | 6 | 5 | 0 | 0 | 0 | 0 |
| **Group B** | 105 | 86.1 | 17 | 13.9 | 0 | 0 | 0 | 0 |
| **z=2.385; p=0.017** | | | | | | | | |
| **Pruritus** | | | | | | | | |
| **Group A** | 90 | 74.4 | 24 | 19.8 | 7 | 5.8 | 0 | 0 |
| **Group B** | 83 | 68 | 31 | 25.4 | 8 | 6.6 | 0 | 0 |
| **z=1.051; p=0.293** | | | | | | | | |

**Table 3:** Comparison of final outcome between two study groups

| **Outcome** | **Group A (n=121)** | | **Group B (n=122)** | | **Total (n=243)** | |
|---|---|---|---|---|---|---|
| | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| Treated | 88 | 72.7 | 83 | 68.0 | 171 | 70.4 |
| Not treated | 33 | 27.3 | 39 | 32.0 | 72 | 29.6 |

$\chi^2$=0.642; p=0.423

**Table 4:** Comparison of Duration of achievement of complete response between two study groups

| **Follow up** | **Group A (n=88)** | | **Group B (n=83)** | | **Total (n=161)** | |
|---|---|---|---|---|---|---|
| | **No.** | **%** | **No.** | **%** | **No.** | **%** |
| 4 weeks | 23 | 26.1 | 0 | 0.0 | 23 | 13.5 |
| 6 weeks | 65 | 73.9 | 83 | 100.0 | 148 | 86.5 |

$\chi^2$=25.064; p<0.001

**Table 5:** Recurrence of dermatophyte after clinical cure

| Sign | No | | Mild | | Moderate | | Severe | |
|---|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | No. | % |
| **Erythema** | | | | | | | | |
| **Group A** | 84 | 95.5 | 4 | 4.5 | 0 | 0 | 0 | 0 |
| **Group B** | 78 | 94 | 5 | 6 | 0 | 0 | 0 | 0 |
| **z=0.432; p=0.666** | | | | | | | | |
| **Scaling** | | | | | | | | |
| **Group A** | 82 | 93.2 | 6 | 6.8 | 0 | 0 | 0 | 0 |
| **Group B** | 76 | 91.6 | 7 | 8.4 | 0 | 0 | 0 | 0 |
| **z=0.397; p=0.691** | | | | | | | | |
| **Pruritus** | | | | | | | | |
| **Group A** | 83 | 94.3 | 5 | 5.7 | 0 | 0 | 0 | 0 |
| **Group B** | 75 | 90.4 | 8 | 9.6 | 0 | 0 | 0 | 0 |
| **z=0.973; p=0.331** | | | | | | | | |

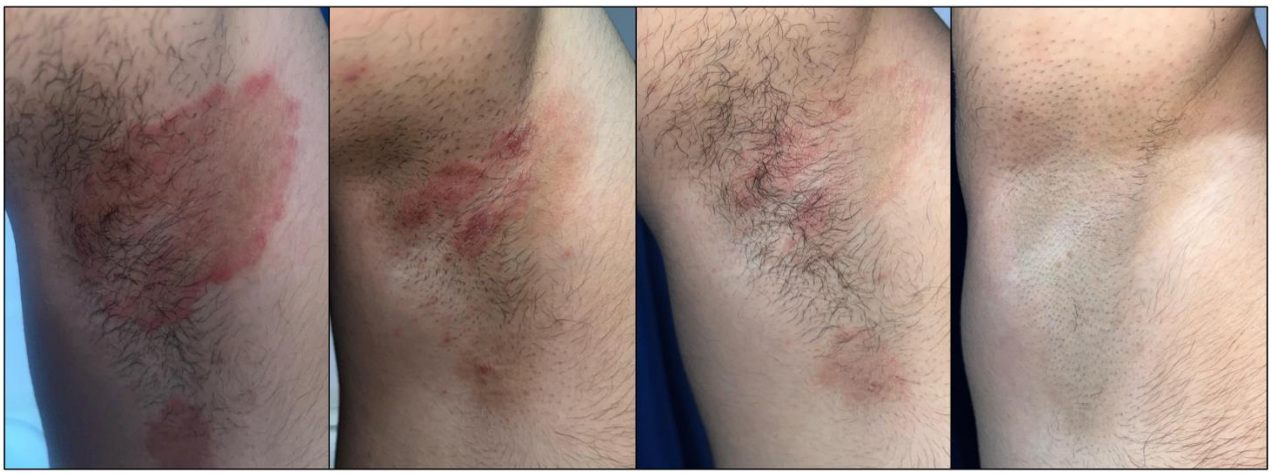

**Figure 1:** Clinical images of Group A (oral itraconazole 100 mg twice daily) at baseline2, 4, and 6 weeks.

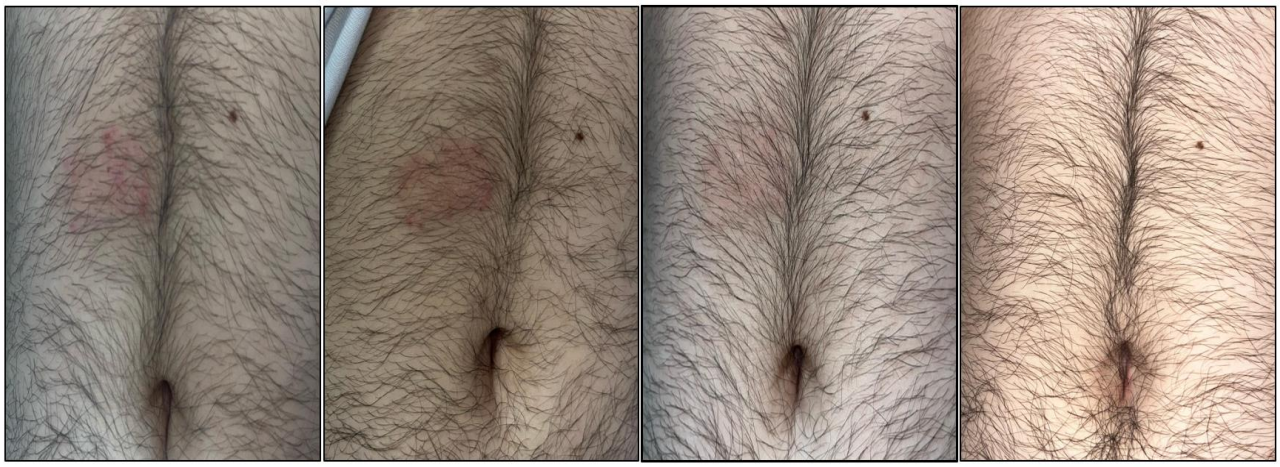

**Figure 2:** Clinical images of Group B (oral Ultramicrosize Griseofulvin 500 mg twice daily) at baseline2, 4, and 6 weeks.

## 4. Discussion

There was a lack of comparative studies evaluating the efficacy of itraconazole and griseofulvin in the treatment of dermatophytosis; therefore, the present study was carried out to compare the clinical efficacy of oral Itraconazole and Ultramicrosized Griseofulvin in the treatment of tinea corporis and cruris. As far as dose selection and duration of treatment are concerned, 100 mg twice daily dose of itraconazole and 500 mg twice daily dose of griseofulvin for a treatment duration of six weeks was selected. Compared to the present study, some of the earlier studies have

reported use of 100 mg daily itraconazole with 500 mg daily dose of griseofulvin with treatment duration ranging from 15 days to six weeks.[22-24] Compared to these studies, in the present study we used twice a day dose for both the drugs and carried out the treatment upto six weeks.

The drug, dose and treatment length combination used in the present study differed from other studies. This is because most of the earlier studies did not show the efficacy of griseofulvin to be better or comparable to itraconazole, however, its affordability and safety[27] attracted us to explore its efficacy at a higher dose and for a longer duration of treatment.

In the present study we used ultramicrosized griseofulvin. Ultramicrosized griseofulvin has also been used earlier by some workers.[22,24,28] There are some studies that have used microsized griseofulvin.[28,29] However, whether this difference in size has any impact on the treatment outcome is yet to be established. In one study that used both microsized as well as ultramicrosized griseofulvin, the safety profile was found to be similar but no report exists reporting any impact of size of griseofulvin being used. However, pharmacological data suggests that owing to poor solubility in water, ultramicrosized griseofulvin may metabolize better than the microsized griseofulvin.[30]

In the present study, treatment response was evident from the first follow-up at 2 weeks. By the final follow-up, resolution of erythema, scaling, and pruritus was observed in 77.7%, 95.0%, and 74.4% of the Itraconazole group, and 69.7%, 86.1%, and 68.0% of the Ultramicrosized Griseofulvin group, respectively, indicating a proportionally better response in the Itraconazole group, though not statistically significant. The overall cure rates were 72.7% in the Itraconazole group and 68.0% in the Ultramicrosized Griseofulvin group. At final assessment, KOH positivity rates were comparable between groups. Recurrence rates of mild erythema, scaling, and pruritus were slightly higher in the Ultramicrosized Griseofulvin group but without statistical significance. Some patients who were not cured by 6 weeks showed symptomatic improvement in subsequent follow-ups, with a higher proportion of improvement in the Itraconazole group across all symptoms. Overall, while both treatments were comparable in efficacy, Itraconazole demonstrated a faster and more sustained clinical response.

These findings are in contrast with findings of some earlier studies that found proportional drug response to be better in itraconazole as compared to griseofulvin. Panagiotidou *et al.*[23] in their study found cure rate of 77.8% in itraconazole as compared to 66.7% in griseofulvin group patients. However, it may be noted that they recorded this response after 15 days of treatment and for 100 mg/day itraconazole against 500 mg/day griseofulvin. In the present study, however, we not only used the twice amount of dose of both the drugs but also had a much longer treatment duration. Similarly, at 4 weeks, our findings also showed itraconazole to be proportionally better than griseofulvin. Thus, the drug-dose and treatment combination used in the present study differed from their study.

It may also be noted that using a six-week regimen for 100 mg daily itraconazole against ultramicrosized 500 mg daily dose, Lopez-Gomez *et al.*[24] were also able to achieve same drug response (88%) in both the groups which implies that dynamics of drug response is affected by the treatment duration. In the present study, a comparable response of griseofulvin over six week treatment period could thus be attributed to use of two times higher dose of both the drugs (twice a day in the present study as compared to once a day in their study).

Most of the studies reporting superiority of Itraconazole over Griseofulvin have been of much shorter duration of treatment as compared to that in the present study. Moreover, the drug-dose combinations in their studies also varied from that in the present study. Aharya *et al* [26] who compared 100 mg once a day two-week treatment with 250 mg twice a day griseofulvin for 4 weeks found 90.47% improvement rate in itraconazole as compared to 76.2% in griseofulvin group. In their study mycological response was also found to be better in itraconazole (72%) as compared to that in griseofulvin group (57%). In fact, their results could be suggested to be reflective of a short-term therapy as compared to relatively longer treatment (and of course with different regimen) in the present study.

One of the important considerations in treatment of dermatophytosis is treatment cost. The cost of treatment of itraconazole is almost seven times higher as compared to that of Griseofulvin and in that context even a comparable if not better performance of griseofulvin holds an economic value.[27]

## 5. Conclusion

The findings of the present study thus show that ultramicrosize griseofulvin can safely be recommended as a cost-effective alternative to itraconazole for the treatment of dermatophyte infections. One of the limitations of the study was the absence of longer post-treatment follow-up. In the present study, we had only two weeks post-treatment follow-up and hence we are not in a position to comment on long-term post-treatment outcomes in terms of recurrence or relapse. Nevertheless, the findings of the present study are promising and pave the way for multicenter studies with varied drug–dose regimens and longer follow-up to establish long-term efficacy.

## 6. Ethical Approval

This study was approved by Institutional ethical approval committee with ref no. ELMC & H/R-Cell/2023/28.

## 7. Conflict of Interest

None.

## 8. Source of Funding

None.

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