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SESSION II

A 12-week treatment for dermatophyte toe onychomycosis: terbinafine 250 mg/day vs. itraconazole 200 mg/day—a double-blind comparative trial

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Summary Lamisil® (terbinafine) 250 mg daily and itraconazole 200 mg daily were compared in the treatment of dermatophyte toe onychomycosis over 12 weeks in a double-blind randomized clinical trial. At the end of follow-up (week 48) treatment with Lamisil® led to negative mycology in 73% of patients compared with 45·8% in the itraconazole group ($P < 0·0001$). Globally the clinical symptoms of the target nail improved, a response which was in favour of Lamisil® ($P = 0·001$). The percentages of patients who were clinically totally cured or who presented with only minimal symptoms were 76·3% for the Lamisil®-treated group compared with 58·1% in the itraconazole group. The unaffected nail length for big toes was significantly higher in the Lamisil®-treated group (9·1 mm vs. 7·7 mm; $P = 0·0298$). Onycholysis was also less in the Lamisil® group ($P = 0·001$). We conclude that 12 weeks' continuous oral therapy leads to higher cure rates with Lamisil® than with itraconazole and that both drugs are equally well tolerated.

Lamisil® (terbinafine) 250 mg daily for 12 weeks has been shown to be very effective in the treatment of dermatophyte onychomycosis due to its primary fungicidal activity.[1–5]

In this double-blind randomized clinical trial, itraconazole 200 mg daily for 12 weeks was compared with Lamisil® 250 mg daily for the same treatment period.

Method

Patients with a clinical diagnosis of toe onychomycosis confirmed by positive direct microscopy *and* culture for dermatophytes at a central laboratory were included. At each visit (i.e. week 4, 8, 12, 24, 36, 48) clinical symptoms (unaffected nail length, hyperkeratosis, onycholysis and paronychial inflammation) were evaluated and direct microscopy and culture were performed to assess efficacy. During the treatment period, blood analysis of renal and liver function was performed to assess safety.

A total of 186 patients in the Lamisil® group and 186 in the itraconazole group were included in the intention-to-treat analysis.

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Results

Treatment with Lamisil® led to negative mycology at follow-up, defined as negative microscopy *and* negative culture, in 73% of patients, compared with 45·8% in the itraconazole group ($P < 0·0001$) at week 48 (Fig. 1). The 95% confidence intervals for difference between treatments are 27·2% (17%, 37·3%).

Globally, clinical symptoms of the target nail improved more in favour of Lamisil® ($P = 0·001$). Percentages of patients who were clinically totally cured or who had only minimal symptoms were

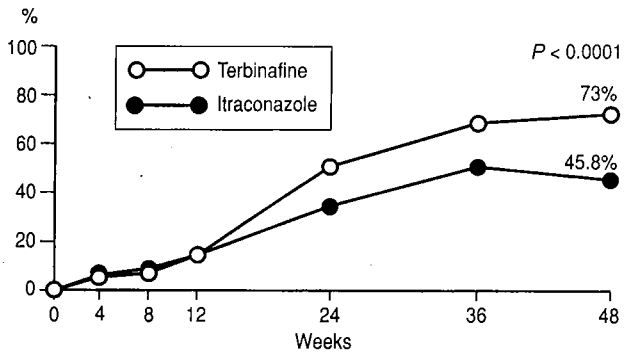

Figure 1. Negative mycology at week 48 (%).

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Table 1. Clinical symptoms at week 48

	Terbinafine		Itraconazole	
Cleared	40·9	76·3	33·1	58·1
Minimal symptoms	35·4		25	
Slightly improved	11		12·8	
Failure	12·8		29·1	
		$P = 0·001$		

76·3% for the Lamisil®-treated group compared with 58·1% in the itraconazole group (Table 1). The 95% confidence intervals for difference between treatments are 18·1% (8·24%, 27·9%).

The unaffected nail length for big toes was significantly greater in the Lamisil®-treated group (9·1 mm vs. 7·7 mm; $P = 0·0298$). The 95% confidence intervals for difference between treatments are 1·4 mm (0·163 mm, 2·64 mm). Onycholysis was also less frequent in the Lamisil® group ($P = 0·001$). No significant difference was observed in hyperkeratosis.

Overall tolerability was rated good to very good in almost 90% of patients in both treatment groups. All the reported adverse events were those known for both compounds and no new unexpected clinically relevant adverse events were detected.

Conclusion

Our results show that 12 weeks' continuous treatment by the oral route gives higher cure rates with Lamisil® than with itraconazole and that both drugs may be equally well tolerated.

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