



Barbara Rinehart

JOURNAL
ARTICLES
ALLERGY:
DERMATITIS

My responsibilities were:

- Worked with agency to develop outline
- Researched medical literature
- Wrote manuscript for author review
- Referenced and annotated manuscript

Comparative Study of the Efficacy and Safety of Loratadine Syrup and Terfenadine Suspension in the Treatment of Chronic Allergic Skin Diseases in a Pediatric Population

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Schieland Hospital¹, Ba Schiedam (The Netherlands), St. John's Hospital for Skin Diseases² London (England), Hospital Peduivies de Coimbra³, Coimbra (Portugal), Dermatological Clinic⁴, Modena (Italy), Hospital Curry Cabral⁵, Lisboa (Portugal), Nij Smellonghe Hospital⁶, Drachten (The Netherlands), Syngrou Hospital⁷, Athens (Greece), Hospital Saint Charles⁸, Montpellier (France), Toronto Western Hospital⁹, Ontario (Canada), Centre Hospitalier Ste-Justine¹⁰, Montreal, Quebec (Canada), Aglatis Kyriakiou Childrens Hospital¹¹, Athens (Greece), and Schering-Plough Research Institute¹², Kenilworth, New Jersey (USA)

Summary

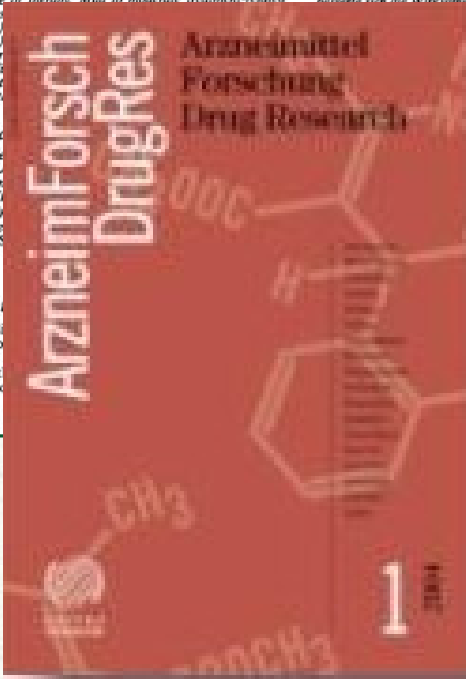
The safety and efficacy of loratadine (Sch 29851, CAS 79794-75-5) syrup (5 or 10 mg QD) was compared to terfenadine (CAS 50679-08-8) suspension (30 mg b.i.d.) in a randomized, third party blind, parallel-group, multicenter trial. Two hundred thirty-six children ages 6-12 years, with chronic allergic skin disorders were treated for 14 days. The predominant skin condition was atopic dermatitis (88% of the efficacy population). Evaluation of efficacy was based on investigator and patient assessment of symptoms, overall condition of the disease, and therapeutic response to treatment. After 7 and 14 days of treatment, and in the endpoint analysis (last valid study visit for all patients), the decreases from baseline in mean total signs/symptom scores, and all individual symptoms, did not differ significantly ($p > 0.05$) between treatments. Itching improved 54% in the loratadine group and 58% in the terfenadine group in the endpoint analysis. Forty-five percent of patients treated with loratadine and 46% of terfenadine-treated patients had complete or marked relief of their symptoms at endpoint. The efficacy of loratadine increased during the study, suggesting that patients did not develop tolerance to the medication over the 14-day course of therapy. Mild to moderate treatment-related adverse events were reported in 6% of patients in the loratadine group and 9% in the terfenadine group. No serious adverse events were reported in either group. The safety and efficacy of loratadine and terfenadine were comparable. Loratadine and terfenadine were found to be equally effective in the treatment of chronic allergic skin diseases in a pediatric population.

Zusammenfassung
Vergleich von Loratadin und Terfenadin bei Kindern mit chronischen allergischen Hauterkrankungen

1. In der vorliegenden Studie wurde die Sicherheit und Wirksamkeit von Loratadin (Sch 29851, CAS 79794-75-5) Syrup (5 oder 10 mg QD) mit Terfenadin (CAS 50679-08-8) Suspension (30 mg b.i.d.) in einer randomisierten, drittpartei-blind, parallelgruppierten, multicenter Studie verglichen. 236 Kinder im Alter zwischen 6 und 12 Jahren mit chronischen Hautallergien wurden über 14 Tage behandelt. Die Haupterkrankung in der Untersuchungsgruppe war ein atopisches Ekzem (88% des Wirksamkeitskollektivs). Die Beurteilung der Wirksamkeit basierte auf der Bewertung der Untersucher und der Patienten hinsichtlich der Symptome, des allgemeinen Krankheitszustandes und der therapeutischen Erfolge der Behandlung. Nach jeweils 7 und 14 Behandlungstagen sowie bei der Endanalyse (letzter geltender Untersuchungsbesuch sämtlicher Patienten) konnte kein wesentlicher Unterschied ($p > 0,05$) zwischen den beiden Behandlungsmethoden festgestellt werden, weder hinsichtlich des Abfalls von Ausgangswert für durchschnittliche Anzeichen-/Symptomwerte noch hinsichtlich der einzelnen Symptome der Teilnehmer. Am Endpunkt zeigte die Loratadin-Gruppe eine Verbesserung von 54% hinsichtlich Juckreiz, während die Verbesserung dieses Symptoms bei der Terfenadin-Gruppe bei 58% lag. Am Endpunkt wiesen 45% der mit Loratadin behandelten Patienten und 46% der mit Terfenadin behandelten Patienten eine vollständige oder erhebliche Verbesserung ihrer Symptome auf. Während der Studie verzeichnete die Loratadin-Gruppe eine Zunahme der Toleranz gegenüber dem Medikament, was zu der Beobachtung führte, dass die Wirksamkeit von Loratadin im Laufe einer 14-tägigen Behandlung zunahm, was darauf hindeutet, dass Patienten im Laufe einer 14-tägigen Behandlung keine Toleranz gegenüber dem Medikament entwickelten. Die Wirksamkeit von Loratadin und Terfenadin war vergleichbar. Die Sicherheit und Wirksamkeit von Loratadin und Terfenadin waren in der Behandlung von chronischen allergischen Hauterkrankungen bei Kindern vergleichbar. Loratadin konnten als gut verträglich und wirksam bei der Behandlung von chronischen allergischen Hauterkrankungen bei Kindern angesehen werden.

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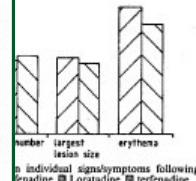
pro Tag) mit Terfenadin (CAS 50679-08-8)-Suspension (30 mg zweimal täglich) auf Sicherheit und Wirksamkeit verglichen. 236 Kinder im Alter zwischen 6 und 12 Jahren mit chronischen Hautallergien wurden über 14 Tagen behandelt. Die Haupterkrankung in der Untersuchungsgruppe war ein atopisches Ekzem (88% des Wirksamkeitskollektivs). Die Beurteilung der Wirksamkeit basierte auf der Bewertung der Untersucher und der Patienten hinsichtlich der Symptome, des allgemeinen Krankheitszustandes und der therapeutischen Erfolge der Behandlung. Nach jeweils 7 und 14 Behandlungstagen sowie bei der Endanalyse (letzter geltender Untersuchungsbesuch sämtlicher Patienten) konnte kein wesentlicher Unterschied ($p > 0,05$) zwischen den beiden Behandlungsmethoden festgestellt werden, weder hinsichtlich des Abfalls von Ausgangswert für durchschnittliche Anzeichen-/Symptomwerte noch hinsichtlich der einzelnen Symptome der Teilnehmer. Am Endpunkt zeigte die Loratadin-Gruppe eine Verbesserung von 54% hinsichtlich Juckreiz, während die Verbesserung dieses Symptoms bei der Terfenadin-Gruppe bei 58% lag. Am Endpunkt wiesen 45% der mit Loratadin behandelten Patienten und 46% der mit Terfenadin behandelten Patienten eine vollständige oder erhebliche Verbesserung ihrer Symptome auf. Während der Studie verzeichnete die Loratadin-Gruppe eine Zunahme der Toleranz gegenüber dem Medikament, was zu der Beobachtung führte, dass die Wirksamkeit von Loratadin im Laufe einer 14-tägigen Behandlung zunahm, was darauf hindeutet, dass Patienten im Laufe einer 14-tägigen Behandlung keine Toleranz gegenüber dem Medikament entwickelten. Die Wirksamkeit von Loratadin und Terfenadin war vergleichbar. Die Sicherheit und Wirksamkeit von Loratadin und Terfenadin waren in der Behandlung von chronischen allergischen Hauterkrankungen bei Kindern vergleichbar. Loratadin konnten als gut verträglich und wirksam bei der Behandlung von chronischen allergischen Hauterkrankungen bei Kindern angesehen werden.



effect on the signs and symptoms of the disease was prohibited. Chronic medications for all indications not contributory to skin disease were continued.

evaluations

Based on investigator and parental assessment of symptoms, overall condition of the disease, and therapeutic response to treatment. The primary efficacy variable was the decrease from baseline in mean total signs/symptom scores. A combined score of itching and erythema was used as the primary efficacy variable. A combined score of itching and erythema was used as the primary efficacy variable. A combined score of itching and erythema was used as the primary efficacy variable. A combined score of itching and erythema was used as the primary efficacy variable.



itching and lesions.

Severity	Loratadine (n = 94)	Terfenadine (n = 98)
itching and erythema		
Lesion count (eczema, macules, papules, or plaques)	9	9
none	6-12	6-12
one to six	84	90
seven to twelve	8	4
more than twelve	2	4
of largest lesion/largest dimension	87	87
five at plaque	8	4
≤ 2.5 cm	6	5
> 2.5 cm	1-12	1-11
≤ 4 mm	7	6
> 4 mm	3-32	3-18

overall condition of skin.

Definition	Loratadine (n = 94)	Terfenadine (n = 98)
Virtually no symptoms were present. Symptoms were greatly improved and although present, were scarcely troublesome.	44	55
Symptoms were present and troublesome but were noticeably improved.	30	44
Symptoms still present and only minimal improvement was obtained.	20	29
Worse, no relief, symptoms unchanged.	4	10

therapeutic response.

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Worse, no relief, symptoms unchanged.	4	10

in disorders, pediatric: CAS 75-5 - Loratadine, clinical studies

ence other mediators in addition of inducing itch, the connection symptomatology of skin dermatitis is somewhat unclear. Antihistamines including dimetindene, have been used successfully in the treatment of atopic eczema [1]. In a randomized, double-blind, parallel-group, multicenter study, the efficacy and safety of loratadine and terfenadine were compared in the treatment of chronic allergic skin diseases in a pediatric population.

Forsch./Drug Res. 43 (II), Nr. 11 (1993) Lutsky et al. - Loratadine and terfenadine

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from baseline were 40% in the loratadine group and 46% in the terfenadine group. Forty-five percent of patients treated with loratadine and 46% of terfenadine-treated patients had complete or marked relief of their symptoms at endpoint. The efficacy of loratadine increased during the study, suggesting that patients did not develop tolerance to the medication over the 14-day course of therapy. Mild to moderate treatment-related adverse events were reported in 6% of patients in the loratadine group and 9% in the terfenadine group. No serious adverse events were reported in either group. The safety and efficacy of loratadine and terfenadine were comparable. Loratadine and terfenadine were found to be equally effective in the treatment of chronic allergic skin diseases in a pediatric population.

Endpoint analysis showed that 69% (65/94) of the loratadine group and 64% (63/98) of the terfenadine group had mild or no disease symptoms. Mean scores showed that there was no difference in the overall condition of the skin between the two groups.

skin condition

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overall condition of skin.

Endpoint analysis showed that 69% (65/94) of the loratadine group and 64% (63/98) of the terfenadine group had mild or no disease symptoms. Mean scores showed that there was no difference in the overall condition of the skin between the two groups.

ect alone [2-4]. Although it is controversial regarding use in atopic dermatitis, it exists to justify use of agents disease.

24] conducted a single-blind study of terfenadine twice daily (10 mg once daily in children) and found significant improvement in symptoms, with the exception of erythema seen between the two drugs. Studies using loratadine in the treatment of atopic dermatitis found that loratadine was superior to terfenadine [21-23, 25, 26].

Comparing pediatric doses of loratadine and terfenadine in atopic dermatitis confirms the safety and efficacy of loratadine in the treatment of atopic dermatitis, demonstrating that loratadine is as effective as terfenadine in the treatment of atopic dermatitis in children 6 to 12 years of age.

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