

PRISMA I Trial

Background

- Early morning hours usually show a sharp rise in blood pressure (BP) associated with awakening.
- The onset of cerebro- and cardiovascular events, such as sudden death, myocardial infarction and stroke follows a similar daily rhythm that maps the peaks and troughs of BP, with the highest incidence during the early morning hours.

Aim

- To compare the efficacy of telmisartan and ramipril, in reducing ambulatory BP compared with baseline during the last 6 h of the 24-h dosing interval.

Study design

- Prospective, randomized, open-label, blinded-endpoint study

Study patients

- 801 patients with mild to moderate hypertension

Study groups

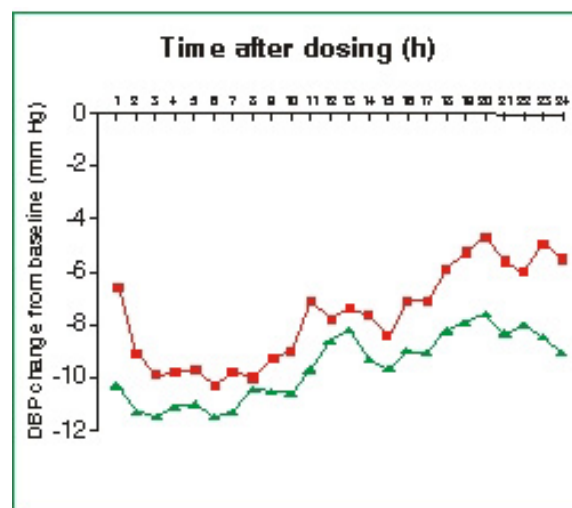
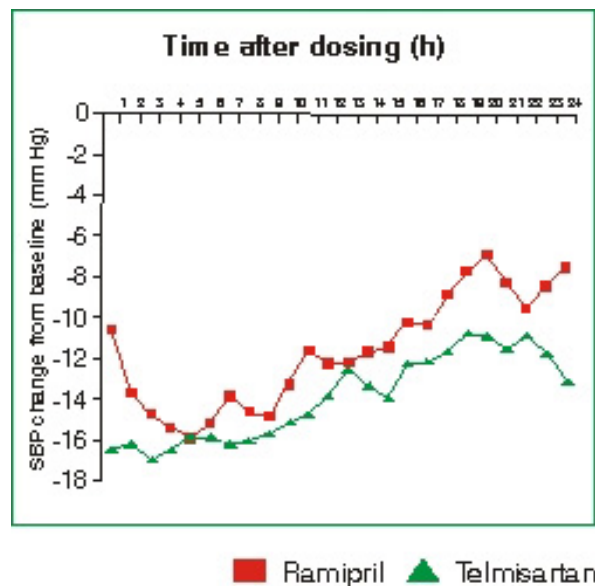
- Telmisartan initiated at 40 mg and titrated to 80 mg after 2 weeks
- Ramipril initiated at 2.5 mg for 2 weeks, titrated to 5mg for 6 weeks and then to 10 mg for a further 6 weeks.

Study duration

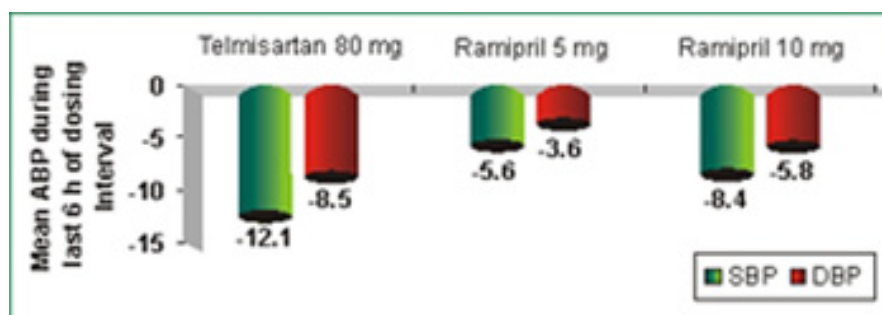
- Group 1: Telmisartan 80 mg vs. Ramipril 5 mg for 8 weeks
- Group 2: Telmisartan 80 mg vs. Ramipril 10 mg for 14 weeks

Results

- Consistently greater reduction in BP throughout the 24-h dosing interval with telmisartan 80 mg compared with ramipril 5 and 10 mg after 8 and 14 weeks of treatment.

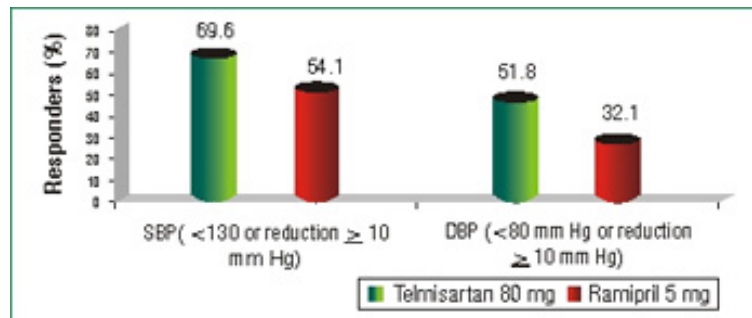


- Superior reduction in mean ambulatory BP during the last 6 h of the dosing interval with telmisartan 80 mg as compared to ramipril 5 mg and 10 mg.



- Greater ambulatory BP response rates in telmisartan-treated patients than among those

treated with ramipril 5 and 10 mg.



- Significantly greater reductions in 24-h, morning, daytime and nighttime mean ambulatory BP with telmisartan 80 mg as compared to ramipril 5 mg and 10 mg.
- Fewer treatment-related adverse events occurred in patients receiving telmisartan than in those receiving ramipril (6.5% vs. 10.1%). Cough (most commonly reported drug-related adverse event) was reported by 5.7% patients in ramipril group as compared to 0.5% in telmisartan group.

Conclusion

- Telmisartan was consistently and significantly more effective than ramipril in controlling BP during the last 6 h of the dosing interval, a time when patients are at greatest risk of cardio- and cerebrovascular events. Both drugs were equally well tolerated, but telmisartan was associated with fewer instances of cough.