AstraZeneca

I-688-B

SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Losec™

ACTIVE INGREDIENT: Omeprazole

Trial Title (number):Prevention of symptom recurrence during maintenance treatment with omeprazole 10 mg once daily or ranitidine 150 mg b.i.d for twelve months.

Development Phase:Phase IV
First Subject Recruited: April 1994
Last Subject Completed: May 1997
Approval Date: 01 August 2007

OBJECTIVES

To determine the time to recurrence of reflux symptoms over a 12 months period by comparing treatment with either omeprazole 10 mg once daily or ranitidine 150 mg b.i.d. To investigate whether there were differences between the two treatment groups with regard to QoL.

METHODS

Study design

Randomized, double blind, parallel-group, multi-centre study.

Target subject population and sample size

Asymptomatic patients from study I-688-A, informed consent, aged between 10 and 80 years. Total of 300 subjects.

Investigational product and comparator(s): dosage, mode of administration and batch numbers

Omeprazole 10 mg and ranitidine 150 mg b.i.d.

Duration of treatment

Asymptomatic patients were treated for maximally 12 months with either omeprazole 10 mg or ranitidine 150 mg b.i.d. Patients with recurrence of their reflux symptoms during follow-up left the study.

Criteria for evaluation

Assessment methods

Symptoms rating, quality of life questionnaires.

Statistical methods

Survival analysis, log-rank test (symptoms relief) and two-way ANOVA (QoL).

RESULTS

Summary of results

The estimated proportion of patients in symptomatic remission after 12 months maintenance treatment were 68% and 39% in the omeprazole 10 mg o.m. and ranitidine 150 mg b.i.d. groups, respectively (p<0.0001). The time to recurrence was influenced by the treatment in the acute phase of the study. The period was the longest for the sequence ran/ome; ome/ome; ome/ran; ran/ran. The QoL – evaluated by the GSRS – was better maintained with omeprazole 10 mg o.m. than with ranitidine 150 mg b.i.d.

After correction for the number of treatment days the number of Adverse Events reported by treatment group were equal.

Additional safety information is presented in Table 1.

Table 1 Long-term omeprazole study data

Trial	Treatment	Omep dose (mg)	Planned duration (months	N	Average days of treatment	Total exposure (pt-yrs)	% dropouts	# CV SAEs	# deaths all cause	# deaths CV	# MIs	# MI fatal	# deaths or MIs	# Non heam. stroke
I-688-B	Omeprazole	10	12	134	365.0	133.9	16.4	1	0	0	0	0	0	0
	Ranitidine		12	129	365.0	128.9	8.5	0	0	0	0	0	0	0

(mg milligram; N number of patients; CV Cardiovascular; SAE Serious adverse event; MI Myocardial infarction.)

As with any comprehensive clinical trial programme, individual studies may include both approved and non-approved treatment regimens, including doses higher than those approved for clinical use. Before prescribing Losec™ (omeprazole), Healthcare Professionals should view their specific country information.