AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: ATACAND®
ACTIVE INGREDIENT: candesartan

Study No: NIS-CSI-ATA-2005/1, NCT 00837720
Evaluation of Atacand® (candesartan) in daily practice

Developmental phase: Post-marketing non-interventional study
Study Completion Date: June 2007
Date of Report: September 2008

OBJECTIVES:

This InPractice Evaluation Programme consisted of a 3-month non-interventional follow-up of hypertensive patients who were prescribed Atacand (candesartan) at the discretion of their treating physician. The objective of the study was to obtain information on practical experience with Atacand therapy.

The following objectives were set for the study:

Primary objective

Evaluation of antihypertensive efficacy of Atacand in hypertensive patients based on the difference between both systolic and diastolic blood pressure levels (mmHg) at baseline in comparison to the first and the second follow-up visit.

Secondary objectives

Frequency and reasons of treatment discontinuation.

Patient treatment satisfaction (assessed using a 5-point scale) as a measure of patient's overall treatment tolerance.

Physician overall evaluation of the therapy (assessed using a 5-point scale).

METHODS:

The study was performed as a 12-week open, non-randomised follow-up study. The study involved hypertensive patients prescribed Atacand at the discretion of their treating physician either as the first-line antihypertensive therapy or as a substitute for their previous antihypertensive therapy that did not provide adequate blood pressure control.

Any additional therapy (initiation, adjustment, discontinuation) for hypertension as well as therapy for any concomitant conditions was decided upon by the treating physicians clinical judgement and according to the current professional guidelines. All additional therapy had to be duly documented in the questionnaires.

As the study was not comparative but observational, the basic methodological assumption was that it monitors a single population.

The treatment efficacy was assessed by measurement of blood pressure and heart rate in accordance with the Slovenian hypertension management guidelines; measurements were performed by treating physicians at each of the three visits during the study (Annex II).

Occurrence of adverse events had to be documented by organ systems. Serious adverse events had to be reported to the Agency of Medicinal Products and Medical Devices of RS as legally required.

Patient treatment satisfaction and physician overall evaluation of the therapy were assessed using 5-point Likert scales.

Data were collected using questionnaires (Annex III) completed by the treating physician. At the baseline visit (at enrolment) the following data were collected: gender, age, body height, body weight, duration of hypertension (either newly diagnosed or time since the first diagnosis), any additional risk factors (smoking, diabetes mellitus), antihypertensive therapy received to this visit, any additional therapy (because of concomitant conditions), blood pressure, heart rate. At the first follow-up visit (after 6 weeks) the following data were collected: Atacand dose, blood pressure, heart rate, any changes in the relevant concomitant therapy, physician and patient treatment satisfaction, any adverse effects since the baseline visit, and, in case of treatment discontinuation, reason for discontinuation. At the second follow-up visit (after 12 weeks) the following data were collected: Atacand dose, blood pressure, heart rate, any changes in the relevant concomitant therapy, physician and patient treatment satisfaction, any adverse effects since the previous (first follow-up) visit, and, in case of treatment discontinuation, reason for discontinuation.

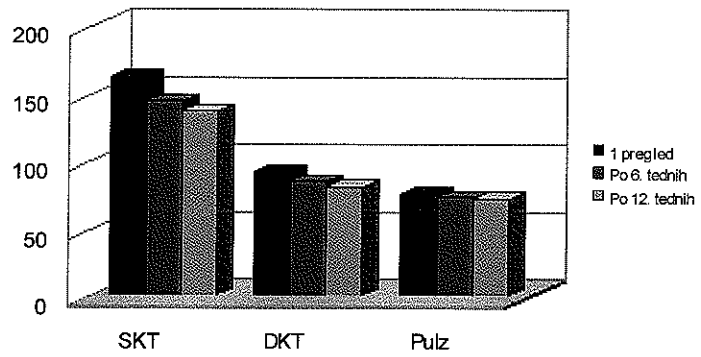
RESULTS:

Primary objective

Efficacy of the antihypertensive therapy

Efficacy was evaluated by differences of both systolic and diastolic blood pressure levels at the first and at the second follow-up visit in comparison to levels at the baseline visit.

Diagram 1. Effectiveness of Atacand therapy (all differences are statistically significant).



Patients came for a follow-up visit after 6 weeks. They were receiving Atacand at the dosage shown in Table 1. The majority of patients were receiving 16 mg Atacand in a single daily dose.

Table 1. Daily dosage of Atacand (mg)

	Frequency	Percent	Valid Percent	Cumulative Percent
	1	0.1	0.1	0.1
12	1	0.1	0.1	0.3
16	150	20.0	20.0	20.3
2	1	0.1	0.1	20.4
24	1	0.1	0.1	20.5
32	4	0.5	0.5	21.1
4	109	14.5	14.5	35.6
8	460	61.3	61.3	96.9
Atacand Plus 16/12.5	23	3.1	3.1	100.0
Total	750	100.0	100.0	

The blood pressure after 6 weeks of treatment is shown in Table 2.

Table 2. Blood pressure and heart rate after 6 weeks

	N	Minimum	Maximum	Mean	Std. Deviation
Blood pressure systolic	749	100.00	200.00	144.4833	16.03868
Blood pressure diastolic	740	50.00	120.00	85.0757	9.39811
Heart rate	744	42.00	125.00	73.4677	9.29241
Valid N (listwise)	710				

Following 12 weeks of therapy patients were on average receiving doses of Atacand stated in the Table 3; with this dosage their blood pressure levels were as shown in the Table 4.

Table 3. Daily dosage of Atacand (mg)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		25	3.3	3.3	3.3
	12	2	0.3	0.3	3.6
	16	270	36.0	36.0	39.6
	2	1	0.1	0.1	39.7
	24	1	0.1	0.1	39.9
	30	3	0.4	0.4	40.3
	32	34	4.5	4.5	44.8
	4	71	9.5	9.5	54.3
	8	307	40.9	40.9	95.2
	Atacand plus 16/12.5	36	4.8	4.8	100.0
	Total	750	100.0	100.0	

Table 4. Blood pressure and heart rate after 12 weeks

	N	Minimum	Maximum	Mean	Std. Deviation
Systolic blood pressure	727	105.00	200.00	136.8143	13.69331
Blood pressure diastolic	725	54.00	120.00	81.4966	8.11411
Heart rate	727	52.00	110.00	72.3824	8.29664
Valid N (listwise)	710				

Secondary objectives

Table 5. Frequency of treatment discontinuation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		1	0.1	0.1	0.1
	YES	2	0.3	0.3	0.4
	YES drug allergy	1	0.1	0.1	0.5
	YES shortness of breath, feeling unwell	1	0.1	0.1	0.7
	YES cough	1	0.1	0.1	0.8
	YES intolerance to active ingredients	1	0.1	0.1	0.9
	YES non-cooperation	2	0.3	0.3	1.2
	YES cough	1	0.1	0.1	1.3
	YES incompliance	1	0.1	0.1	1.5
	YES reporting palpitations and fast heart rate	1	0.1	0.1	1.6
	NO	738	98.4	98.4	100.0
	Total	750	100.0	100.0	

Only 1.6% of patients discontinued Atacand therapy; reasons for discontinuation were very non-specific as shown in the Table 5.

Patient treatment satisfaction

As shown in Tables 6 and 7, the vast majority of patients were satisfied with Atacand therapy: only 1.5% reported not to be satisfied.

Table 6. Patient satisfaction with Atacand therapy after 6 weeks of treatment

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	5	5	0.7	0.7	0.7
	1	11	1.5	1.5	2.1
	2	11	1.5	1.5	3.6
	3	110	14.7	14.7	18.3
	4	260	34.7	34.7	52.9
	5	353	47.1	47.1	100.0
	Total	750	100.0	100.0	

Table 7. Patient satisfaction with Atacand therapy after 12 weeks of treatment

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	20	20	2.7	2.7	2.7
	1	8	1.1	1.1	3.7
	2	6	0.8	0.8	4.5
	3	30	4.0	4.0	8.5
	4	228	30.4	30.4	38.9
	5	458	61.1	61.1	100.0
	Total	750	100.0	100.0	

Physician treatment satisfaction

Table 8. Physician satisfaction with Atacand therapy after 6 weeks of treatment

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		6	0.8	0.8	0.8
	1	8	1.1	1.1	1.9
	2	38	5.1	5.1	6.9
	3	123	16.4	16.4	23.3
	4	247	32.9	32.9	56.3
	5	328	43.7	43.7	100.0
	Total	750	100.0	100.0	

Table 9. Physician satisfaction with Atacand therapy after 12 weeks of treatment

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		23	3.1	3.1	3.1
	1	4	0.5	0.5	3.6
	2	16	2.1	2.1	5.7
	3	35	4.7	4.7	10.4
	4	183	24.4	24.4	34.8
	5	489	65.2	65.2	100.0
	Total	750	100.0	100.0	