Boehringer Ingelheim

Clinical Study Synopsis for Public Disclosure

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The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

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A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country..

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Name of company: Boehringer Ingelheim		**Tabulated Trial Report**	Boehringer Ingelheim
Name of finished product: Not applicable		**EudraCT No.:** 2007-002410-19	
Name of active ingredient: Telmisartan and amlodipine		**Page:** 1 of 8	**Synopsis No.:**
Module:		**Volume:**	
Disclosure Synopsis date: 10 JUL 2014	**Trial No. / U No.:** 1235.7 / U09-1516-01	**Dates of trial:** 07 FEB 2008 – 20 MAR 2009	**Date of revision** (if applicable)**:** Not applicable

Title of trial:	An open label follow-up trial of the efficacy and safety of chronic administration of the combination of telmisartan 40 mg + amlodipine 5 mg or the combination of telmisartan 80 mg + amlodipine 5 mg tablets alone or in combination with other antihypertensive medications in patients with hypertension
Coordinating Investigator:	[redacted]
Trial sites:	Multi-national, multi-centre trial in 120 centres in 12 countries across Europe, Asia, North America and Africa
Publication (reference):	Data of this study have not been published
Clinical phase:	III
Objectives:	The primary objective of this study was to assess the efficacy and safety of the fixed-dose combinations (FDC) of telmisartan 40 mg/amlodipine 5 mg (T40/A5), and telmisartan 80 mg/amlodipine 5 mg (T80/A5) alone or in addition to other antihypertensive therapies during open-label treatment for at least 6 months.
Methodology:	This was an open-label trial starting with an initial 4-week treatment with T40/A5. Patients who showed inadequate BP control (defined as DBP ≥90 mmHg) at Week 4 or Week 8 were uptitrated to the higher strength FDC of T80/A5. At subsequent visits (Weeks 8, 14 and 22) additional antihypertensive medications were added, if there was inadequate DBP control. Trough seated BP was measured 24 h post-dose at each visit.
No. of subjects:	
planned:	entered: 976
actual:	enrolled: 976
	Treatment: Telmisartan 40 mg + Amlodipine 5 mg (T40/A5) entered:589 treated:589 analysed (for primary endpoint): 578 Treatment: Telmisartan 80mg + Amlodipine 5mg (T80/A5) entered: 387 treated: 387 analysed (for primary endpoint): 387

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Diagnosis and main criteria for inclusion:	Adult patients with previously uncontrolled essential hypertension (seated DBP ≥95 mmHg in previously treated patients; seated DBP ≥100 mmHg in treatment naïve patients), who were randomised to and completed the preceding trial 1235.5 in the previous 14 days. The preceding trial 1235.5, was a randomised, parallel, double-blind comparison of T40/A5, T80/A5, amlodipine 5 mg (A5) and amlodipine 10 mg (A10) for 8 weeks. All patients who were randomised in 1235.5 had failed to respond to treatment with A5 alone. (Failure to respond was defined as DBP ≥90 mmHg after 6 weeks of treatment with A5 alone).
Test product:	Telmisartan 40 mg/amlodipine 5 mg FDC
dose:	1 tablet (40mg/5mg) once daily
mode of admin.:	oral
batch no.:	Visits 1,2,3: B071002461, B071002443, Visits 3,4,5- B071002706, Visits 4,5- B081002986
Test product:	Telmisartan 80 mg/amlodipine 5 mg FDC
dose:	1 tablet (80mg/5mg) once daily
mode of admin.:	oral
batch no.:	Visits 2,3- B071002456, B071002446, Visits 4,5- B071002707, B081002989
Reference therapy:	Not applicable
dose:	
mode of admin.:	
batch no.:	
Duration of treatment:	Up to 34 weeks

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Criteria for evaluation:

Efficacy: The primary efficacy endpoint was the proportion of patients achieving diastolic blood pressure (DBP) control (mean seated DBP <90 mmHg at trough i.e. 24 h after last dose) at the end of this open-label trial.

Secondary endpoints were mean changes in trough DBP and SBP, trough DBP control (DBP <80 mmHg), trough SBP control (SBP <140 mmHg), trough DBP and SBP response, proportion of patients in the trough BP categories (optimal, normal, high-normal, Stage 1 and Stage 2 hypertension), proportion of patients requiring up-titration to T80/A5 to achieve DBP control, proportion of patients on T40/A5 and T80/A5 requiring additional antihypertensive medication to achieve DBP control, the additional reduction in BP with the use of additional antihypertensive medication(s) and the time of starting the additional antihypertensive medication(s).

Safety: Safety was monitored by assessment of adverse events (AEs), laboratory parameters, vital signs, and change in body weight. Abnormalities in 12-lead electrocardiogram (ECG) if any, was reported as AEs.

Statistical methods: Only descriptive statistics were used for all endpoints.

SUMMARY – CONCLUSIONS:

Efficacy results: Out of 1046 patients who completed the trial 1235.5, 976 patients (93.3%) participated in this open-label follow-up trial; 930 of the 976 patients (95.3%) completed the study; 46 (4.7%) patients discontinued the study prematurely. The distribution of patients by the last dose received prior to the end of study visit and intake of additional antihypertensive medication(s) was: T40/A5: 564, T80/A5: 206; T40/A5+: 25, and T80/A5+: 181. Important protocol violations (PV) were noted in 15.1% of the patients. In the treated population, 76.4% were whites, 62.6% were males and the mean age of patients was 53.9 years. The mean duration of hypertension was 5.6 years at the beginning of the preceding trial 1235.5. The mean trough seated BP (SBP/DBP) at baseline of the preceding trial, i.e. after a 6-week, open-label treatment with A5, was 149.5/96.7 mmHg and at the end of the preceding trial, 137.9/88.1 mmHg.

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Efficacy results: (continued)

Summary of Efficacy results / FAS

	T40/A5	T80/A5	T40/A5+	T80/A5+
Patients, n (%)	553 (100.0)	206 (100.0)	25 (100.0)	181 (100.0)
Primary endpoint				
DBP control <90 mmHg, n (%)				
Baseline 1235.5	2 (0.4)	0	0	0
End trial 1235.5	408 (73.8)	82 (39.8)	10 (40.0)	22 (12.2)
End open-label trial	504 (91.1)	160 (77.7)	19 (76.0)	84 (46.4)
Secondary endpoints				
Mean change in BP (SBP/DBP) at end of open-label trial, (mmHg)				
Change from baseline 1235.5	−17.8/ −14.2	−15.9/ −12.6	−12.6/−9.5	−14.0/−10.2
Change from end trial 1235.5	−4.1/−3.5	−5.6/−5.5	−3.6/−5.5	−7.2/−5.7
DBP control <80 mmHg, n (%)				
Baseline 1235.5	0	0	0	0
End trial 1235.5	118 (21.3)	14 (6.8)	0	3 (1.7)
End open-label trial	202 (36.5)	35 (17.0)	1 (4.0)	9 (5.0)
SBP control <140 mmHg, n (%)				
Baseline 1235.5	142 (25.7)	35 (17.0)	6 (24.0)	18 (9.9)
End 1235.5	367 (66.4)	96 (46.6)	12 (48.0)	52 (28.7)
End open-label trial	440 (79.6)	142 (68.9)	16 (64.0)	89 (49.2)
DBP response, n (%)				
End 1235.5	420 (75.9)	97 (47.1)	12 (48.0)	42 (23.2)
End open-label trial	504 (91.1)	171 (83.0)	19 (76.0)	108 (59.7)
SBP response, n (%)				
End trial 1235.5	428 (77.4)	132 (64.1)	16 (64.0)	88 (48.6)
End open-label trial	490 (88.6)	179 (86.9)	18 (72.0)	128 (70.7)
BP <140/90 mmHg (BP categories: optimal, normal and high-normal), n(%)				
Baseline 1235.5	0	1 (0.1)	0	0
End trial 1235.5	311 (56.3)	50 (24.2)	8 (32.0)	12 (6.7)
End open-label trial	418 (75.6)	125 (60.7)	13 (52.0)	52 (28.7)

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Efficacy results: (continued)

At baseline of the preceding trial 1235.5, 0.2% of the patients in the full analysis set (FAS) had DBP control (trough seated DBP <90 mmHg); at the end of the preceding trial 1235.5 (EOT 1235.5), 54.1% of the patients achieved trough DBP control, which increased to 79.5% at the end of this open-label trial. This means that the DBP control rates were not only maintained, but also improved during this open-label trial leading to a high proportion of patients achieving DBP control at the end. The randomised treatments (pre-A5: 78.1%; pre-A10: 79.6%; pre-T40/A5: 79.7% and pre-T80/A5: 80.6%) patients had received in trial 1235.5, did not impact on the DBP control rates at the end of this open-label trial. The results for the primary endpoint for the per protocol analysis set confirmed the results for the FAS.

In general, the results of secondary endpoints were consistent with the results obtained for the primary endpoint. At baseline of the preceding trial 1235.5, the trough seated BP (SBP/DBP) was 149.5/96.7 mmHg. This reduced to 137.9/88.1 mmHg at EOT 1235.5 and further to 132.9/83.7 mmHg at the end of this open-label trial, i.e. an overall reduction of −16.6/−13.0 mmHg for both trials and a reduction of −5.0/−4.4 mmHg during this open-label trial. This shows that clinically relevant additional BP reductions were observed during this open-label trial.

From baseline to EOT 1235.5 to end of this open-label trial, the proportion of patients who achieved DBP <80 mmHg increased from 0 to 14.0% to 25.6%; SBP control (SBP <140 mmHg) increased from 20.8% to 54.6% to 71.2%. From EOT 1235.5 to the end of this open-label trial, the overall trough seated DBP response (DBP <90 mmHg or a reduction of ≥10 mmHg in trough DBP) increased from 59.2% to 83.1% and trough seated SBP response rates (SBP <140 mmHg or a reduction of ≥15 mmHg in trough SBP) increased from 68.8% to 84.5%.

At baseline of the preceding trial 1235.5, 0.1% of the patients had the recommended target BP (SBP/DBP <140/90 mmHg). This increased to 39.5% at EOT 1235.5, and further to 63.0% at the end of this open-label trial.

A total of 218 patients out of 965 (22.6%) were prescribed additional antihypertensive medication(s) at some time during this open-label trial, mostly at or after 14 weeks of treatment (Visit 3). A total of 206 patients (out of 965, 21.3%) did not have DBP control prior to the intake of additional

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Efficacy results: (continued)	antihypertensive medication(s); 12 patients (out of 965, 1.2%) had prior DBP control, but nevertheless started additional antihypertensive medication(s). Among the patients who did not have trough DBP control before addition of antihypertensive medication (n=206), 100 patients (out of 206, 48.5%) achieved DBP control at the visit after the intake. In the analysis of the trough DBP control (DBP <90 mmHg) pre- and post-uptitration to T80/A5, 378 patients (out of 965, 39.2%) were uptitrated (only patients with pre- and post trough BP values considered), 361 patients (out of 965, 37.4%) did not have DBP control before uptitration to T80/A5 and 190 patients (out of 361, 52.6%) achieved DBP control post uptitration. This shows that uptitration of patients treated withT40/A5 to T80/A5 was essential to achieve DBP control in more patients.
Safety results:	The median exposure was 238 days, i.e. 34 weeks. As expected due to the trial design, median exposure to T40/A5 was greater than to T80/A5. The median exposures by dose groups were: T40/A5: 217 days (31 weeks) and T80/A5: 205 days (29.3 weeks). During the treatment with T40/A5, 381 patients (39.0%) reported AEs, while 201 patients (50.6%) reported AEs during T80/A5 treatment. It should be noted that the mean exposure for T40/A5 was shorter than for T80/A5 and consequently, when AEs were exposure adjusted, comparable results were observed between the T80/A5 (96.7 patients with events per 100 PY) and the T40/A5 (94.5 patients with events per 100 PY) groups. The most frequently reported AEs were from the system organ class infections and infestations (T40/A5: 13.1%; T80/A5: 18.9%). Oedema peripheral (T40/A5: 3.3%; T80/A5: 5.3%) and back pain (T40/A5: 2.6%; T80/A5: 6.0%) were the most frequently reported PTs. The reported PTs (oedema peripheral, back pain, headache, palpitations, and dizziness) are well known side effects of telmisartan or amlodipine monotherapies. Analysis of the frequency of AEs during the first 4 weeks of this open-label trial according to the treatments of trial 1235.5 did not show clinically relevant differences. Adverse events with an onset prior to the start of this open-label trial and which continued in this open-label trial (irrespective of whether they worsened or improved) were reported by 24.9% of the patients. Any of these AEs which

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Safety results: (continued)

worsened during this open-label trial have also been reported as treatment emergent for this open-label trial.

In general, AEs were rarely of severe intensity (T40/A5: 1.7%; T80/A5: 2.3%). Drug-related AEs were reported at a higher frequency with the T80/A5 treatment (7.6%) as compared to the T40/A5 (5.2%) treatment. Oedema peripheral was the most frequent (T40/A5: 2.4%; T80/A5: 2.8%) drug-related AE. A low proportion of patients (T40/A5: 1.2%; T80/A5: 1.0%) discontinued the trial prematurely due to AEs.

There were no deaths reported during this trial; a total of 28 patients (2.9%) reported SAEs. The incidence of SAEs was low in both the T40/A5 (2.3%) group and the T80/A5 (1.5%) group. Acute myocardial infarction and dizziness were each reported for one patient in each treatment group (T40/A5: 0.1%; T80/A5: 0.3%) and were thus the most frequently reported SAEs. One SAE (coronary artery disease) was reported to be immediately life threatening and requiring hospitalisation. One SAE (hypotonia) was considered to be related to the treatment with T80/A5. Only 3 patients (0.3%) discontinued from the trial due to SAEs. There were 4 patients who were reported to have had SAEs (non-drug related) with an onset in trial 1235.5 that continued in this open-label trial. These SAEs did not worsen during this open-label trial. One non-serious AE (incisional hernia) had its onset in trial 1235.5, worsened during the course of the open-label trial and was reported as an SAE in this trial. Other significant AEs were reported for a total of 15 patients (1.5%); 1.1% of the patients in the T40/A5 group and 1.0% of the patients in the T80/A5 group. In total, only 3 patients (0.3%) in the T40/A5 group discontinued due to oedema peripheral (most frequent PT) and one patient in the T80/A5 group (0.3%) had dose reduction due to oedema peripheral as an AE.

There were no laboratory abnormalities reported as SAEs. Increased blood creatine phosphokinase was reported as an AE leading to treatment discontinuation for one patient. No safety concerns for the clinical laboratory parameters arose during the conduct of this trial. No relevant changes were reported for mean pulse rate and patient weight during this trial.

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Conclusions:	Long-term (at least 6 months), open-label treatment with the FDCs T40/A5 and T80/A5 was effective in achieving trough DBP <90 mmHg for the vast majority of patients (79.5%), who were non-responders to A5 monotherapy. The proportion of patients who received additional antihypertensive medication(s) was low (22.6%). Clinically relevant mean reductions in SBP/DBP were achieved in all treatment groups. The results observed at the end of this open-label trial were independent of the treatments that patients had received in the preceding double-blind trial. Open-label treatment with T40/A5 and T80/A5 was well tolerated. The safety data obtained were consistent with the known safety profiles of telmisartan and amlodipine.

Trial Synopsis - Appendix

The appended tables on the following pages supplement the trial results presented in the Trial Synopsis. They complement results for the primary and secondary endpoints of the trial. Note that not all endpoints defined in the trial protocol are presented in this synopsis because their number was too large to allow meaningful presentation in this format.

Results for	**presented in**
Patient disposition	Table 15.1.1: 2
Patients achieving DBP control at 6 months (Primary endpoint)	Table 15.2.1: 2
Change in SBP from baseline of preceding trial to 6 months (Secondary endpoint)	Table 15.2.4: 2
Change in DBP from baseline of preceding trial to 6 months (Secondary endpoint)	Table 15.2.3: 2
Change in SBP from end of preceding trial to 6 months (Secondary endpoint)	Table 15.2.4: 4
Change in DBP from end of preceding trial to 6 months (Secondary endpoint)	Table 15.2.3: 4
Time to first and duration of additional antihypertensives (Secondary endpoint)	Table 15.2.7: 1
Reduction in BP by use of additional antihypertensive medication(s) (Secondary endpoint)	Table 15.2.7: 4

Table 15.1.1: 2 Disposition of patients - enrolled set

	T40/A5 N (%)	T80/A5 N (%)	T40/A5+ N (%)	T80/A5+ N (%)	Total N (%)
Enrolled					976
Not entered/randomised					0
Entered/randomised	564	206	25	181	976
Not treated	0	0	0	0	0
Treated	564 (100.0)	206 (100.0)	25 (100.0)	181 (100.0)	976 (100.0)
Not prematurely discontinued trial medication	529 (93.8)	198 (96.1)	24 (96.0)	179 (98.9)	930 (95.3)
Prematurely discontinued from trial medication	35 (6.2)	8 (3.9)	1 (4.0)	2 (1.1)	46 (4.7)
Adverse event	14 (2.5)	4 (1.9)	0 (0.0)	0 (0.0)	18 (1.8)
AE study disease worsening	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
AE other disease worsening	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
AE other	13 (2.3)	4 (1.9)	0 (0.0)	0 (0.0)	17 (1.7)
Lack of efficacy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Non compliant with protocol	12 (2.1)	2 (1.0)	1 (4.0)	2 (1.1)	17 (1.7)
Lost to follow-up	6 (1.1)	1 (0.5)	0 (0.0)	0 (0.0)	7 (0.7)
Consent withdrawn	3 (0.5)	1 (0.5)	0 (0.0)	0 (0.0)	4 (0.4)
Other	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 15.2.1: 2 Last dose level subgroup comparison of trough DBP control (<90mmHg) at the end of study - full analysis set

Trough DBP control 1	T40/A5	T80/A5	T40/A5+	T80/A5+
Number of patients	553	206	25	181
Trough DBP control 1 [N (%)]				
N	553 (100.0)	206 (100.0)	25 (100.0)	181 (100.0)
No (DBP >= 90 mmHg)	49 (8.9)	46 (22.3)	6 (24.0)	97 (53.6)
Yes (DBP < 90 mmHg)	504 (91.1)	160 (77.7)	19 (76.0)	84 (46.4)
Comparison to T40/A5				
Odds ratio		0.34	0.31	0.08
95% CI		(0.22 , 0.53)	(0.12 , 0.81)	(0.06 , 0.13)
Comparison to T80/A5				
Odds ratio			0.91	0.25
95% CI			(0.34 , 2.41)	(0.16 , 0.39)
Comparison to T40/A5+				
Odds ratio				0.27
95% CI				(0.10 , 0.72)

Table 15.2.4: 2 Last dose level subgroup comparison of change from baseline (Randomisation visit of 1235.5) to the end of study in trough SBP - full analysis set

Trough mean SBP [mmHg] #	T40/A5 (N=549)	T80/A5 (N=203)	T40/A5+ (N=24)	T80/A5+ (N=176)
Baseline 1235.5				
Mean (SE)	147.51 (0.51)	151.11 (0.86)	148.06 (2.06)	154.01 (0.94)
End of study				
Mean (SE)	129.72 (0.55)	135.20 (0.83)	135.46 (2.37)	139.97 (0.99)
Change to end of study				
Mean (SE)	-17.79 (0.52)	-15.91 (0.86)	-12.60 (2.50)	-14.04 (0.92)
Difference to T40/A5				
Mean (SE)		1.44 (2.66)	-1.87 (1.26)	-3.75 (1.06)
95% confidence interval		(-3.78, 6.67)	(-4.34, 0.61)	(-5.83, -1.67)
Difference to T80/A5				
Mean (SE)			-3.31 (2.64)	-5.19 (2.55)
95% confidence interval			(-8.50, 1.87)	(-10.20, -0.18)
Difference to T40/A5+				
Mean (SE)				-1.88 (1.01)
95% confidence interval				(-3.86, 0.09)

= N´s exclude patients from the analysis set with incomplete data

Table 15.2.3: 2 Last dose level subgroup comparison of change from baseline (Randomisation visit of 1235.5) to the end of study in trough DBP - full analysis set

Trough mean DBP [mmHg] #	T40/A5 (N=549)	T80/A5 (N=203)	T40/A5+ (N=24)	T80/A5+ (N=176)
Baseline 1235.5				
Mean (SE)	95.12 (0.17)	97.73 (0.37)	96.18 (0.90)	100.35 (0.42)
End of study				
Mean (SE)	80.94 (0.29)	85.09 (0.44)	86.71 (0.85)	90.18 (0.52)
Change to end of study				
Mean (SE)	-14.18 (0.31)	-12.64 (0.52)	-9.47 (1.51)	-10.17 (0.56)
Difference to T40/A5				
Mean (SE)		0.70 (1.61)	-2.47 (0.76)	-4.01 (0.64)
95% confidence interval		(-2.45, 3.85)	(-3.96, -0.97)	(-5.26, -2.76)
Difference to T80/A5				
Mean (SE)			-3.16 (1.59)	-4.71 (1.54)
95% confidence interval			(-6.29, -0.04)	(-7.73, -1.69)
Difference to T40/A5+				
Mean (SE)				-1.54 (0.61)
95% confidence interval				(-2.73, -0.36)

= N´s exclude patients from the analysis set with incomplete data

Table 15.2.4: 4 Last dose level subgroup comparison of change from end of preceding study 1235.5 to the end of study in trough SBP - full analysis set

Trough mean SBP [mmHg] #	T40/A5 (N=545)	T80/A5 (N=203)	T40/A5+ (N=24)	T80/A5+ (N=180)
End of study 1235.5				
Mean (SE)	133.77 (0.56)	140.82 (0.90)	139.06 (2.14)	146.97 (0.95)
End of study				
Mean (SE)	129.63 (0.55)	135.20 (0.83)	135.46 (2.37)	139.80 (0.97)
Change to end of study				
Mean (SE)	-4.14 (0.50)	-5.62 (0.83)	-3.60 (2.41)	-7.17 (0.88)
Difference to T40/A5				
Mean (SE)		3.57 (2.56)	1.55 (1.21)	3.03 (1.01)
95% confidence interval		(-1.45, 8.60)	(-0.82, 3.92)	(1.04, 5.02)
Difference to T80/A5				
Mean (SE)			-2.03 (2.54)	-0.55 (2.46)
95% confidence interval			(-7.02, 2.97)	(-5.37, 4.28)
Difference to T40/A5+				
Mean (SE)				1.48 (0.97)
95% confidence interval				(-0.42, 3.38)

= N´s exclude patients from the analysis set with incomplete data

Table 15.2.3: 4 Last dose level subgroup comparison of change from end of preceding study 1235.5 to the end of study in trough DBP - full analysis set

Trough mean DBP [mmHg] #	T40/A5 (N=545)	T80/A5 (N=203)	T40/A5+ (N=24)	T80/A5+ (N=180)
End of study 1235.5				
Mean (SE)	84.39 (0.33)	90.76 (0.52)	92.22 (1.22)	95.87 (0.48)
End of study				
Mean (SE)	80.84 (0.29)	85.24 (0.44)	86.71 (0.85)	90.13 (0.51)
Change to end of study				
Mean (SE)	-3.54 (0.33)	-5.52 (0.55)	-5.51 (1.59)	-5.74 (0.58)
Difference to T40/A5				
Mean (SE)		0.22 (1.69)	0.21 (0.80)	2.19 (0.67)
95% confidence interval		(-3.09, 3.54)	(-1.35, 1.78)	(0.88, 3.51)
Difference to T80/A5				
Mean (SE)			-0.01 (1.68)	1.97 (1.62)
95% confidence interval			(-3.30, 3.29)	(-1.21, 5.16)
Difference to T40/A5+				
Mean (SE)				1.98 (0.64)
95% confidence interval				(0.72, 3.23)

= N´s exclude patients from the analysis set with incomplete data

Table 15.2.7: 1 Time to first and duration of additional antihypertensives - full analysis set

	Total
Number of patients	965
Time to first other antihypertensive [days]	
N	218
Mean	85.8
SD	38.4
Min	16
Median	64.0
Max	200
Duration of other antihypertensive [days]	
N	218
Mean	145.4
SD	43.2
Min	14
Median	157.0
Max	222

Table 15.2.7: 4 Trough DBP and SBP pre- and post- additional antihypertensives - full analysis set

	Trough DBP [mmHg] (N=965)		Trough SBP [mmHg] (N=965)	
	Actual	Change	Actual	Change
Pre-antihypertensive				
N	218		218	
Mean	95.33		146.34	
SD	5.46		12.14	
Min	77.3		113.3	
Median	94.67		147.17	
Max	116.7		230.7	
Post-antihypertensive				
N	218	218	218	218
Mean	89.59	-5.73	138.81	-7.53
SD	6.64	7.65	13.10	11.21
Min	71.3	-31.0	106.0	-46.7
Median	89.67	-4.67	139.33	-6.67
Max	109.3	12.7	185.0	24.0

Note: Only patients taking additional antihypertensives summarised
Pre-antihyper.: trough BPs taken prior to starting CT, end of study 1235.5 used if necessary
Post-antihyper.: trough BPs taken from the last visit during 1235.7