ID: TAK-491CLD_302 | Efficacy and Safety of Azilsartan Medoxomil Combined With Chlorthalidone in Participants With Moderate to Severe Hypertension | NCT00847626

Results Preview

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Participant Flow

Recruitment Details: Participants enrolled at 175 investigative sites in Austria, Chile, Germany, Guatemala, Mexico, Netherlands, Peru, Poland, Russian Federation and the United States from 29 January 2009 to 10 July 2010.

Pre-Assignment Details: Participants with moderate to severe essential hypertension were enrolled in one of 11, once-daily (QD) treatment groups.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD	Total (Not public)
Arm/Group Description	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	
Period Title: Overall Study												
Started	156	154	147 [1]	156	153	162 [2]	157 [3]	160 [4]	155	153	162	1715
Completed	135	131	131	125	125	125	135	141	141	139	142	1470
Not Completed	21	23	16	31	28	37	22	19	14	14	20	245
Reason Not Completed												
Adverse Event	10	10	6	19	11	22	4	6	3	6	6	103
Protocol Violation	2	1	2	1	1	1	1	1	0	1	1	12
Lost to Follow-up	0	1	1	1	0	3	1	3	1	0	1	12
Withdrawal by Subject	5	5	3	8	12	9	8	4	4	5	2	65
Lack of Efficacy	3	1	0	1	2	0	6	2	5	1	7	28
Other	1	5	4	1	2	2	2	3	1	1	3	25
NOTE : "Other" is not sufficiently descriptive for "Other" Reason Not Completed. Please provide a more descriptive label.												
(Not Public)	Not Completed = 21 Total from all reasons = 21	Not Completed = 23 Total from all reasons = 23	Not Completed = 16 Total from all reasons = 16	Not Completed = 31 Total from all reasons = 31	Not Completed = 28 Total from all reasons = 28	Not Completed = 37 Total from all reasons = 37	Not Completed = 22 Total from all reasons = 22	Not Completed = 19 Total from all reasons = 19	Not Completed = 14 Total from all reasons = 14	Not Completed = 14 Total from all reasons = 14	Not Completed = 20 Total from all reasons = 20	

[1] Includes participant who was randomized but did not receive study medication.

[2] Includes participant who was randomized but did not receive study medication.

[3] Includes participant who was randomized but did not receive study medication.

[4] Includes participant who was treated with double-blind study medication but not randomized.

Baseline Characteristics

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD	Total
Arm/Group Description	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	
Overall Number of Baseline Participants	156	154	147	156	153	162	157	159	155	153	162	**1714**
Baseline Analysis Population Description	[Not specified]											
Age, Continuous **Mean (Standard Deviation)** **Units: years**	58.2 (10.57)	57.4 (11.13)	56.2 (10.50)	57.4 (11.07)	55.8 (11.22)	57.6 (11.04)	57.3 (11.30)	56.2 (10.04)	57.3 (11.04)	57.8 (10.28)	57.3 (10.87)	57.2 (10.82)
Age, Customized **Measure Type: Number** **Units: participants**												
<45 years	15	16	17	21	25	19	21	18	18	17	16	203
Between 45 to 64 years	98	97	100	93	90	104	97	108	97	98	107	1089
≥65 years	43	41	30	42	38	39	39	33	40	38	39	422
Gender, Male/Female **Measure Type: Number** **Units: participants**												
Female	86	77	76	85	82	100	74	90	87	68	84	909
Male	70	77	71	71	71	62	83	69	68	85	78	805
Ethnicity (NIH/OMB) **Measure Type: Number** **Units: participants**												
Hispanic or Latino	10	19	11	15	19	15	17	19	20	17	15	177
Not Hispanic or Latino	90	75	76	85	71	87	84	86	77	80	86	897
Unknown or Not Reported	56	60	60	56	63	60	56	54	58	56	61	640
Race (NIH/OMB) **Measure Type: Number** **Units: participants**												
American Indian or Alaska Native	9	13	13	13	12	16	14	14	11	13	14	142
	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.		NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	NOTE : The sum of participants in all Categories for the Measure does not equal the Overall Number of Baseline Participants in the Arm/Group.	
Asian	4	3	4	4	2	3	1	7	1	1	4	34
Native Hawaiian or Other Pacific Islander	0	1	0	0	0	0	1	0	0	0	0	2
Black or African American	34	28	29	30	26	34	31	29	31	35	35	342
White	111	112	102	111	114	109	111	111	113	105	111	1210
More than one race	2	2	1	2	1	0	1	2	1	1	2	15
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0	0	0
Region of Enrollment **Measure Type: Number** **Units: participants**												
Austria	1	0	0	0	1	0	0	0	0	0	0	2
Chile	3	3	3	2	2	3	2	1	2	3	2	26
Germany	4	6	6	5	6	5	4	5	3	4	5	53
Guatemala	8	8	9	10	10	8	8	9	8	9	9	96
Mexico	10	11	11	9	12	11	11	8	13	11	12	119
Netherlands	6	7	6	5	7	5	6	6	6	6	7	67
Peru	11	12	13	12	12	14	12	11	13	12	12	134
Poland	8	8	7	8	8	8	7	8	8	7	8	85
Russian Federation	5	5	5	5	5	6	6	6	5	4	6	58
United States	100	94	87	100	90	102	101	105	97	97	101	1074
Height **Mean (Standard Deviation)** **Units: cm**	166.3 (11.71)	166.6 (10.85)	167.1 (11.44)	166.8 (11.64)	166.6 (10.81)	165.4 (10.79)	168.3 (11.07)	166.1 (11.36)	166.4 (10.65)	167.7 (12.27)	167.1 (11.85)	166.8 (11.32)
Weight **Mean (Standard Deviation)** **Units: kg**	89.85 (22.076)	86.06 (18.056)	89.28 (21.484)	90.16 (21.949)	87.31 (19.209)	86.44 (20.412)	89.12 (21.049)	86.70 (20.270)	87.27 (18.934)	87.54 (19.019)	86.27 (20.354)	87.80 (20.289)
Body Mass Index (BMI)												

Mean (Standard Deviation)												
Units: kg/m^2	32.2 (5.73)	31.0 (5.65)	31.8 (6.57)	32.2 (6.01)	31.4 (5.84)	31.5 (6.28)	31.2 (5.85)	31.2 (5.78)	31.3 (5.23)	31.0 (5.85)	30.8 (6.28)	31.4 (5.92)
Smoking Status												
Measure Type: Number												
Units: participants												
Never smoked	94	84	81	79	91	94	93	91	92	90	94	983
Current smoker	22	28	25	35	26	28	25	29	25	31	29	303
Ex-smoker	40	42	41	42	36	40	39	39	38	32	39	428
Estimated glomerular filtration rate (eGFR) [1]												
Measure Type: Number												
Units: participants												
≥0 and <30	0	0	0	0	0	0	0	0	0	1	0	1
≥30 and <60	13	14	6	8	6	10	12	9	11	11	8	108
≥60 and <90	95	90	93	97	109	110	101	100	94	95	99	1083
≥90	48	50	48	51	38	42	44	50	49	46	55	521
Missing	0	0	0	0	0	0	0	0	1	0	0	1

[1] eGFR based on calculated creatinine clearance.
Categories:
Normal renal function (≥90 mL/min/1.73 m2) Mild renal impairment(60 to <90 mL/min/1.73 m2) Moderate renal impairment (30 to <60 mL/min/1.73 m2) Severe renal impairment (0 to <30 mL/min/1.73 m2)
Includes all randomized participants

Outcome Measures

1. Primary Outcome

Title: Change From Baseline to Week 8 in Trough, Systolic Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring (Pooled Analysis)

Description: The change in trough systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough is the average of all measurements recorded from 22 to 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD**	**Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 80 mg QD**
Arm/Group Description:	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks. OR Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	228	134	127
Least Squares Mean (Standard Error) Units: mmHg	-28.9 (0.89)	-15.9 (1.16)	-15.1 (1.19)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	Analysis of covariance model (ANCOVA) using treatment as a fixed effect and baseline as a covariate was performed. Results for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD pool were obtained using contrast with coefficients of 0.5 for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and 0.5 for Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD from the ANCOVA model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Net)
	Estimated Value	-13.0
	Confidence Interval	(2-Sided) 95% -15.8 to -9.5
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed. Results for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD pool were obtained using contrast with coefficients of 0.5 for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and 0.5 for Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD from the ANCOVA model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-13.8
	Confidence Interval	(2-Sided) 95% -16.7 to -10.9
	Estimation Comments	[Not specified]

2. Primary Outcome

Title: Change From Baseline to Week 8 in Trough, Systolic Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring (Pairwise Analysis)

Description: The change in trough systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough is the average of all measurements recorded from 22 to 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD**	**Chlorthalidone 12.5 mg QD**	**Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 20 mg QD**	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally,	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally,	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally,	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally,	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally,	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally,	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally,	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally,	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally,

	once daily for up to 8 weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.	up to 8 weeks.	weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.	once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-22.9 (1.19)	-26.3 (1.24)	-24.4 (1.24)	-29.8 (1.26)	-26.3 (1.28)	-28.0 (1.26)	-12.7 (1.18)	-15.9 (1.16)	-12.1 (1.19)	-12.8 (1.17)	-15.1 (1.19)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	< 0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-10.3
	Confidence Interval	(2-Sided) 95% -13.6 to -7.0
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-10.4
	Confidence Interval	(2-Sided) 95% -13.7 to -7.0
	Estimation Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-11.8
	Confidence Interval	(2-Sided) 95% -15.1 to -8.4
	Estimation Comments	[Not specified]

Statistical Analysis 4

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)

	Estimated Value	-13.9
	Confidence Interval	(2-Sided) 95% -17.3 to -10.6
	Estimation Comments	[Not specified]

Statistical Analysis 5

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-13.7
	Confidence Interval	(2-Sided) 95% -17.1 to -10.3
	Estimation Comments	[Not specified]

Statistical Analysis 6

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-12.0
	Confidence Interval	(2-Sided) 95% -15.4 to -8.7
	Estimation Comments	[Not specified]

Statistical Analysis 7

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 20 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-10.9
	Confidence Interval	(2-Sided) 95% -14.2 to -7.6
	Estimation Comments	[Not specified]

Statistical Analysis 8

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 20 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-14.2
	Confidence Interval	(2-Sided) 95% -17.6 to -10.9
	Estimation Comments	[Not specified]

Statistical Analysis 9

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 40 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA

	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-11.6
	Confidence Interval	(2-Sided) 95% -15.0 to -8.3
	Estimation Comments	[Not specified]

Statistical Analysis 10

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 40 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-17.0
	Confidence Interval	(2-Sided) 95% -20.4 to -13.6
	Estimation Comments	[Not specified]

Statistical Analysis 11

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-11.2
	Confidence Interval	(2-Sided) 95% -14.7 to -7.8
	Estimation Comments	[Not specified]

Statistical Analysis 12

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-12.8
	Confidence Interval	(2-Sided) 95% -16.2 to -9.4
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title: Change From Baseline to Week 8 in Trough, Sitting, Clinic Systolic Blood Pressure

Description: The change in trough systolic blood pressure measured at final visit or week 8 relative to baseline. Systolic blood pressure is the arithmetic mean of the 3 serial trough sitting systolic blood pressure measurements.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD**	**Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD**	**Chlorthalidone 12.5 mg QD**	**Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 20 mg QD**	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	154	153	145	155	151	158	155	156	155	152	162
Least Squares Mean (Standard Error) Units: mmHg	-33.8 (1.26)	-37.0 (1.26)	-36.8 (1.30)	-39.5 (1.25)	-36.9 (1.27)	-40.1 (1.24)	-21.1 (1.25)	-27.1 (1.25)	-19.8 (1.26)	-23.3 (1.27)	-24.2 (1.23)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-12.7
	Confidence Interval	(2-Sided) 95% -16.2 to -9.2
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-9.9
	Confidence Interval	(2-Sided) 95% -13.4 to -6.4
	Estimation Comments	[Not specified]

Statistical Analysis 3

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-15.7
	Confidence Interval	(2-Sided) 95% -19.2 to -12.1
	Estimation Comments	[Not specified]

Statistical Analysis 4

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-12.4
	Confidence Interval	(2-Sided) 95% -15.8 to -8.9
	Estimation Comments	[Not specified]

Statistical Analysis 5

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD, Chlorthalidone 12.5 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-15.8
	Confidence Interval	(2-Sided) 95% -19.3 to -12.3
	Estimation Comments	[Not specified]

Statistical Analysis 6

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD, Chlorthalidone 25 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-13.0
	Confidence Interval	(2-Sided) 95% -16.5 to -9.5
	Estimation Comments	[Not specified]

Statistical Analysis 7

Statistical Analysis Overview	Comparison Groups	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 20 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-14.0
	Confidence Interval	(2-Sided) 95% -17.5 to -10.5
	Estimation Comments	[Not specified]

Statistical Analysis 8

Statistical Analysis Overview	Comparison Groups	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 20 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-17.2
	Confidence Interval	(2-Sided) 95% -20.6 to -13.7
	Estimation Comments	[Not specified]

Statistical Analysis 9

Statistical Analysis Overview	Comparison Groups	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 40 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-13.5
	Confidence Interval	(2-Sided) 95% -17.0 to -9.9
	Estimation Comments	[Not specified]

Statistical Analysis 10

Statistical Analysis Overview	Comparison Groups	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 40 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-16.2
	Confidence Interval	(2-Sided) 95% -19.7 to -12.7
	Estimation Comments	[Not specified]

Statistical Analysis 11

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-12.8
	Confidence Interval	(2-Sided) 95% -16.3 to -9.3
	Estimation Comments	[Not specified]

Statistical Analysis 12

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-16.0
	Confidence Interval	(2-Sided) 95% -19.4 to -12.6
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title: Change From Baseline to Week 8 in Trough Systolic Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Black Participants (Pooled Analysis)

Description: The change in trough systolic blood pressure in black subjects measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough is the average of all measurements recorded from 22 to 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD**	**Chlorthalidone 25 mg QD**	**Azilsartan Medoxomil 80 mg QD**
Arm/Group Description:	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks. OR Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	40	22	28
Least Squares Mean (Standard Error) Units: mmHg	-28.2 (2.49)	-23.4 (3.36)	-9.9 (2.97)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed. Results for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and Azilsartan Medoxomil 80mg/Chlorthalidone 25 mg QD pool were obtained using contrast with coefficients of 0.5 for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and 0.5 for Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD from the ANCOVA model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.255
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-4.8
	Confidence Interval	(2-Sided) 95% -13.0 to 3.5
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg or 80 mg/Chlorthalidone 25 mg QD, Azilsartan Medoxomil 80 mg QD
	Comments	ANCOVA using treatment as a fixed effect and baseline as a covariate was performed. Results for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and Azilsartan Medoxomil 80mg/Chlorthalidone 25 mg QD pool were obtained using contrast with coefficients of 0.5 for Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD and 0.5 for Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD from the ANCOVA model.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<0.001
	Comments	Tested at 5% significance level.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-18.2

Confidence Interval (2-Sided) 95%
-25.9 to -10.6

Estimation Comments [Not specified]

5. Secondary Outcome

Title: Change From Baseline to Week 8 in Trough Systolic Blood Pressure as Measured by Ambulatory Blood Pressure Monitoring in Black Participants (Pairwise Analysis)

Description: The change in trough systolic blood pressure in black participants as measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough is the average of all measurements recorded from 22 to 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	24	22	24	19	18	21	24	22	26	27	28
Least Squares Mean (Standard Error) Units: mmHg	-27.2 (3.21)	-25.4 (3.36)	-21.5 (3.21)	-31.9 (3.61)	-24.8 (3.71)	-24.4 (3.43)	-12.2 (3.22)	-23.4 (3.36)	-10.7 (3.10)	-11.0 (3.04)	-9.9 (2.97)

6. Secondary Outcome

Title: Change From Baseline to Week 8 in Trough, Sitting, Clinic Diastolic Blood Pressure

Description: The change in trough diastolic blood pressure measured at final visit or week 8 relative to baseline. Diastolic blood pressure is the average of the 3 serial trough clinic sitting diastolic blood pressure measurements.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	154	153	145	155	151	158	155	156	155	152	162
Least Squares Mean (Standard Error) Units: mmHg	-14.4 (0.72)	-15.5 (0.72)	-15.6 (0.74)	-17.0 (0.72)	-16.9 (0.73)	-18.5 (0.71)	-7.4 (0.72)	-9.2 (0.72)	-6.7 (0.72)	-9.2 (0.73)	-9.9 (0.70)

7. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Trough Diastolic Blood Pressure (22 to 24 Hours After Dosing), as Measured by Ambulatory Blood Pressure Monitoring.

Description: The change in trough diastolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough is the average of all measurements recorded from 22 to 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-13.3 (0.80)	-15.0 (0.83)	-13.5 (0.83)	-17.3 (0.85)	-16.5 (0.86)	-16.1 (0.85)	-6.5 (0.79)	-7.5 (0.78)	-7.9 (0.80)	-7.3 (0.79)	-8.9 (0.80)

8. Secondary Outcome

Title: Change From Baseline to Week 8 in the 24-hour Mean Systolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring

Description: The change in 24-hour mean systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The 24-hour mean is the average of all measurements recorded for 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-24.0 (0.97)	-26.7 (1.01)	-26.1 (1.01)	-30.4 (1.03)	-27.9 (1.04)	-28.1 (1.03)	-10.9 (0.96)	-14.7 (0.95)	-11.7 (0.97)	-12.6 (0.96)	-15.3 (0.97)

9. Secondary Outcome

Title: Change From Baseline to Week 8 in the 24-hour Mean Diastolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring

Description: The change in 24-hour mean diastolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The 24-hour mean is the average of all measurements recorded for 24 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-13.5 (0.60)	-15.0 (0.62)	-14.9 (0.63)	-17.3 (0.64)	-16.5 (0.65)	-15.9 (0.64)	-5.6 (0.59)	-6.7 (0.59)	-6.8 (0.60)	-7.6 (0.59)	-8.8 (0.60)

10. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Daytime (6 AM to 10 PM) Systolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring.
Description: The change in daytime (6am to 10pm) mean systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. Daytime mean is the average of all measurements recorded between the hours of 6 am and 10 pm.
Time Frame: Baseline and Week 8.
Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-24.4 (1.01)	-27.7 (1.05)	-26.7 (1.06)	-31.2 (1.07)	-28.4 (1.09)	-28.5 (1.07)	-10.8 (1.00)	-14.7 (0.99)	-11.7 (1.01)	-12.8 (1.00)	-15.7 (1.01)

11. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Daytime (6 AM to 10 PM) Diastolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring.
Description: The change in daytime (6am to 10pm) mean diastolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. Daytime mean is the average of all measurements recorded between the hours of 6 am and 10 pm.
Time Frame: Baseline and Week 8.
Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-13.7 (0.64)	-15.6 (0.66)	-15.1 (0.66)	-17.6 (0.67)	-16.8 (0.69)	-16.2 (0.67)	-5.6 (0.63)	-6.5 (0.62)	-6.8 (0.64)	-7.7 (0.63)	-9.1 (0.64)

12. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Nighttime (12 AM to 6 AM) Systolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring.
Description: The change in nighttime (12am to 6am) mean systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. Nighttime mean is the average of all measurements recorded between the hours of 12 am and 6 am.
Time Frame: Baseline and Week 8.
Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-22.5 (1.09)	-24.0 (1.13)	-24.3 (1.14)	-28.1 (1.15)	-26.5 (1.17)	-26.3 (1.15)	-11.3 (1.08)	-14.4 (1.06)	-11.8 (1.09)	-11.8 (1.08)	-14.2 (1.09)

13. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Nighttime (12 AM to 6 AM) Diastolic Blood Pressure, as Measured by Ambulatory Blood Pressure Monitoring.
Description: The change in nighttime (12am to 6am) mean diastolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. Nighttime mean is the average of all measurements recorded between the hours of 12 am and 6 am.
Time Frame: Baseline and Week 8.
Safety Issue? No

Outcome Measure Data

Analysis Population Description
Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20	Azilsartan Medoxomil 20	Azilsartan Medoxomil 40	Azilsartan Medoxomil 40	Azilsartan Medoxomil 80	Azilsartan Medoxomil 80	Chlorthalidone 12.5 mg	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20	Azilsartan Medoxomil 40	Azilsartan Medoxomil 80

	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	QD		mg QD	mg QD	mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-12.8 (0.71)	-13.5 (0.73)	-14.4 (0.74)	-16.2 (0.75)	-15.8 (0.76)	-14.9 (0.75)	-6.0 (0.70)	-7.1 (0.69)	-6.9 (0.70)	-7.5 (0.69)	-8.0 (0.71)

14. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Systolic Blood Pressure at 0 to 12 Hours After Dosing, as Measured by Ambulatory Blood Pressure Monitoring.

Description: The change in the 12-hour mean systolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The 12-hour mean is the average of all measurements recorded in the first 12 hours after dosing.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-24.6 (1.07)	-28.0 (1.11)	-27.1 (1.12)	-31.7 (1.13)	-28.5 (1.15)	-28.7 (1.13)	-10.4 (1.06)	-14.5 (1.04)	-11.8 (1.07)	-12.7 (1.05)	-15.8 (1.07)

15. Secondary Outcome

Title: Change From Baseline to Week 8 in the Mean Diastolic Blood Pressure at 0 to 12 Hours After Dosing, as Measured by Ambulatory Blood Pressure Monitoring.

Description: The change in the 12-hour mean diastolic blood pressure measured at final visit or week 8 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The 12-hour mean is the average of all measurements recorded in the first 12 hours after dosing.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	127	118	117	114	110	114	130	134	128	131	127
Least Squares Mean (Standard Error) Units: mmHg	-13.6 (0.68)	-15.6 (0.71)	-15.4 (0.71)	-17.8 (0.72)	-16.8 (0.73)	-16.2 (0.72)	-5.3 (0.67)	-6.3 (0.66)	-6.8 (0.68)	-7.6 (0.67)	-9.2 (0.68)

16. Secondary Outcome

Title: Percentage of Participants Who Achieve a Clinic Systolic Blood Pressure Response at Week 8, as Defined by Clinic Systolic Blood Pressure <140 mm Hg and/or a Reduction of ≥20 mm Hg From Baseline.

Description: Percentage of participants who achieve a clinic systolic blood pressure response measured at week 8, defined as less than 140 mm Hg and/or reduction from baseline of greater than or equal to 20 mm Hg. Systolic blood pressure is the average of the 3 serial trough sitting clinic systolic blood pressure measurements.

Time Frame: Baseline and Week 8

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	154	153	145	155	151	158	155	156	155	152	162
Measure Type: Number Units: percentage of participants	86.4	88.9	90.3	93.5	86.8	94.9	56.1	76.9	53.5	64.5	66.7

17. Secondary Outcome

Title: Percentage of Participants Who Achieve a Clinic Diastolic Blood Pressure Response at Week 8, Defined as Clinic Diastolic Blood Pressure <90 mm Hg and/or a Reduction of ≥10 mm Hg From Baseline.

Description: Percentage of participants who achieve a clinic diastolic blood pressure response measured at week 8, defined as less than 90 mm Hg and/or reduction from baseline of greater than or equal to 10 mm Hg. Diastolic blood pressure is the average of the 3 serial trough sitting clinic diastolic blood pressure measurements.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20	Azilsartan Medoxomil 20	Azilsartan Medoxomil 40	Azilsartan Medoxomil 40	Azilsartan Medoxomil 80	Azilsartan Medoxomil 80	Chlorthalidone 12.5 mg	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20	Azilsartan Medoxomil 40	Azilsartan Medoxomil 80

	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	mg/Chlorthalidone 12.5 mg QD	mg/Chlorthalidone 25 mg QD	QD		mg QD	mg QD	mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	154	153	145	155	151	158	155	156	155	152	162
Measure Type: Number											
Units: percentage of participants	89.6	89.5	87.6	94.8	90.1	96.8	63.9	78.8	60.6	71.1	74.7

18. Secondary Outcome

Title: Percentage of Participants Who Achieve Both a Clinic Systolic and Diastolic Blood Pressure Response at Week 8.

Description: Percentage of participants who achieve both a clinic systolic and diastolic blood pressure response measured at week 8, defined as systolic blood pressure less than 140 mm Hg and/or reduction from baseline of greater than or equal to 20 mm Hg AND diastolic blood pressure less than 90 mm Hg and/or reduction from baseline of greater than or equal to 10 mm Hg . Systolic/diastolic blood pressure is based on the average of the 3 serial trough clinic sitting systolic/diastolic blood pressure measurements.

Time Frame: Baseline and Week 8.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set, defined as all randomized participants who received at least 1 dose of double-blind study medication, with both a baseline value and at least 1 post-baseline value, with last observation carried forward.

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description:	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.
Number of Participants Analyzed	154	153	145	155	151	158	155	156	155	152	162
Measure Type: Number											
Units: percentage of participants	83.1	84.3	84.8	91.0	82.8	93.0	45.8	67.9	39.4	55.3	62.3

Adverse Events

Time Frame	Treatment-emergent adverse events are adverse events that started on or after the first dose of double-blind study drug and no more than 14 days (or 30 days for a serious adverse event) after the last dose of double-blind study drug.
Additional Description	At each visit the investigator had to document any occurrence of adverse events and abnormal laboratory findings. Any event spontaneously reported by the participant or observed by the investigator was recorded, irrespective of the relation to study treatment.
Source Vocabulary Name	MedDRA 13.0
Assessment Type	Systematic Assessment

Arm/Group Title	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
Arm/Group Description	Azilsartan medoxomil 20 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 40 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan 80 mg and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 12.5 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil placebo and chlorthalidone 25 mg combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 20 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 40 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.	Azilsartan medoxomil 80 mg and chlorthalidone placebo combination tablets, orally, once daily for up to 8 weeks.

Serious Adverse Events

	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	3/156 (1.92%)	0/154 (0%)	1/146 (0.68%)	2/156 (1.28%)	2/153 (1.31%)	2/161 (1.24%)	0/156 (0%)	2/160 (1.25%)	2/155 (1.29%)	2/153 (1.31%)	3/162 (1.85%)
Cardiac disorders											
Myocardial ischaemia †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	1/155 (0.65%)	1/153 (0.65%)	0/162 (0%)
Supraventricular tachycardia †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	1/153 (0.65%)	0/162 (0%)
Endocrine disorders											
Inappropriate antidiuretic hormone secretion †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	1/156 (0.64%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Gastrointestinal disorders											
Gastrointestinal haemorrhage †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	1/161 (0.62%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Inguinal hernia strangulated †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Non-cardiac chest pain †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	1/153 (0.65%)	0/162 (0%)
General disorders											
Multi-organ failure †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	1/161 (0.62%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Infections and infestations											
Cellulitis †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	1/160 (0.63%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Endocarditis bacterial †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	1/161 (0.62%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Gangrene †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	1/162 (0.62%)
Uterine infection †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	1/160 (0.63%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Injury, poisoning and procedural complications											
Contusion †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Investigations											
Blood creatinine increased †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	1/153 (0.65%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Blood urea increased †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	1/153 (0.65%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Blood uric acid increased †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	1/153 (0.65%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Heart rate increased †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	1/156 (0.64%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Metabolism and nutrition disorders											
Hypokalaemia †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)											
Renal cell carcinoma †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	1/162 (0.62%)
Nervous system disorders											
Drop attacks †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Metabolic encephalopathy †A	0/156 (0%)	0/154 (0%)	1/146 (0.68%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Radicular syndrome †A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Psychiatric disorders											
Bipolar disorder †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	1/155 (0.65%)	0/153 (0%)	0/162 (0%)
Suicidal ideation †A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	1/155 (0.65%)	0/153 (0%)	0/162 (0%)

Respiratory, thoracic and mediastinal disorders											
Asthma † A	0/156 (0%)	0/154 (0%)	0/146 (0%)	1/156 (0.64%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Dyspnoea † A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	1/153 (0.65%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Pulmonary embolism † A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	1/162 (0.62%)
Vascular disorders											
Aortic aneurysm † A	1/156 (0.64%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Hypotension † A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	1/161 (0.62%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Peripheral arterial occlusive disease † A	0/156 (0%)	0/154 (0%)	0/146 (0%)	0/156 (0%)	0/153 (0%)	0/161 (0%)	0/156 (0%)	0/160 (0%)	0/155 (0%)	0/153 (0%)	1/162 (0.62%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events: 5%

	Azilsartan Medoxomil 20 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 20 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 40 mg/Chlorthalidone 25 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 12.5 mg QD	Azilsartan Medoxomil 80 mg/Chlorthalidone 25 mg QD	Chlorthalidone 12.5 mg QD	Chlorthalidone 25 mg QD	Azilsartan Medoxomil 20 mg QD	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	52/156 (33.33%)	55/154 (35.71%)	40/146 (27.4%)	74/156 (47.44%)	52/153 (33.99%)	67/161 (41.61%)	51/156 (32.69%)	53/160 (33.13%)	25/155 (16.13%)	36/153 (23.53%)	32/162 (19.75%)
Infections and infestations											
Nasopharyngitis † A	8/156 (5.13%)	5/154 (3.25%)	2/146 (1.37%)	7/156 (4.49%)	2/153 (1.31%)	3/161 (1.86%)	6/156 (3.85%)	4/160 (2.5%)	2/155 (1.29%)	7/153 (4.58%)	2/162 (1.23%)
Investigations											
Blood creatine phosphokinase increased † A	3/156 (1.92%)	4/154 (2.6%)	3/146 (2.05%)	10/156 (6.41%)	3/153 (1.96%)	3/161 (1.86%)	6/156 (3.85%)	7/160 (4.37%)	6/155 (3.87%)	7/153 (4.58%)	6/162 (3.7%)
Blood creatinine increased † A	15/156 (9.62%)	19/154 (12.34%)	17/146 (11.64%)	29/156 (18.59%)	18/153 (11.76%)	32/161 (19.88%)	5/156 (3.21%)	9/160 (5.62%)	4/155 (2.58%)	5/153 (3.27%)	6/162 (3.7%)
Blood urea increased † A	1/156 (0.64%)	6/154 (3.9%)	4/146 (2.74%)	8/156 (5.13%)	6/153 (3.92%)	9/161 (5.59%)	0/156 (0%)	4/160 (2.5%)	0/155 (0%)	0/153 (0%)	1/162 (0.62%)
Blood uric acid increased † A	3/156 (1.92%)	9/154 (5.84%)	6/146 (4.11%)	7/156 (4.49%)	9/153 (5.88%)	3/161 (1.86%)	6/156 (3.85%)	5/160 (3.12%)	1/155 (0.65%)	2/153 (1.31%)	1/162 (0.62%)
Metabolism and nutrition disorders											
Hyperuricaemia † A	2/156 (1.28%)	6/154 (3.9%)	4/146 (2.74%)	3/156 (1.92%)	3/153 (1.96%)	10/161 (6.21%)	3/156 (1.92%)	3/160 (1.88%)	0/155 (0%)	0/153 (0%)	0/162 (0%)
Hypokalaemia † A	3/156 (1.92%)	2/154 (1.3%)	0/146 (0%)	5/156 (3.21%)	0/153 (0%)	2/161 (1.24%)	4/156 (2.56%)	19/160 (11.87%)	0/155 (0%)	1/153 (0.65%)	0/162 (0%)
Musculoskeletal and connective tissue disorders											
Muscle spasms † A	8/156 (5.13%)	2/154 (1.3%)	0/146 (0%)	6/156 (3.85%)	2/153 (1.31%)	4/161 (2.48%)	2/156 (1.28%)	0/160 (0%)	2/155 (1.29%)	0/153 (0%)	2/162 (1.23%)
Nervous system disorders											
Dizziness † A	12/156 (7.69%)	17/154 (11.04%)	20/146 (13.7%)	21/156 (13.46%)	19/153 (12.42%)	19/161 (11.8%)	6/156 (3.85%)	5/160 (3.12%)	2/155 (1.29%)	7/153 (4.58%)	6/162 (3.7%)
Headache † A	8/156 (5.13%)	12/154 (7.79%)	1/146 (0.68%)	9/156 (5.77%)	11/153 (7.19%)	11/161 (6.83%)	19/156 (12.18%)	17/160 (10.63%)	13/155 (8.39%)	11/153 (7.19%)	12/162 (7.41%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.0

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The first study related publication will be a multi-center publication submitted within 24 months after conclusion or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

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