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ID: 01-06-TL-491-020 Efficacy and Safety Study of Azilsartan Medoxomil Compared to Ramipril for Treating Essential Hypertension NCT00760214

Results Preview

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Participant Flow

Recruitment Details: Participants enrolled at 122 investigative sites in Bulgaria, Estonia, Finland, Germany, the Netherlands, Poland, Russia, Serbia and Montenegro, Slovakia and Sweden from 24 January 2008 to 21 April 2009.

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

Arm/Group Title	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD	Ramipril 10 mg QD	Total (Not public)
Arm/Group Description	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.	
Period Title: Overall Study				
Started	295	294	296	885
Completed	265	264	255	784
Not Completed	30	30	41	101
Reason Not Completed				
Adverse Event	8	9	12	29
Protocol Violation	3	0	3	6
Lost to Follow-up	0	0	1	1
Withdrawal by Subject	12	14	13	39
Lack of Efficacy	3	2	4	9
Pregnancy	0	0	1	1
Physician Decision	1	1	1	3
Other	3	4	6	13
NOTE : "Other" is not sufficiently descriptive for "Other" Reason Not Completed. Please provide a more descriptive label.				
(Not Public)	Not Completed = 30 Total from all reasons = 30	Not Completed = 30 Total from all reasons = 30	Not Completed = 41 Total from all reasons = 41	

Baseline Characteristics

Arm/Group Title	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD	Ramipril 10 mg QD	Total
Arm/Group Description	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.	
Overall Number of Baseline Participants	295	294	295	**884**
Baseline Analysis Population Description				

[Not specified]				
Age, Customized				
Measure Type: Number				
Units: Participants				
<45 years	40	45	30	115
Between 45 and 64 years	166	168	195	529
≥65 years	89	81	70	240
Gender, Male/Female				
Measure Type: Number				
Units: participants				
Female	136	136	149	421
Male	159	158	146	463

Outcome Measures

1. Primary Outcome

Title: Change From Baseline in Mean Trough Clinic Sitting Systolic Blood Pressure.

Description: The change in mean trough clinic sitting systolic blood pressure measured at final visit or week 24 relative to baseline. Systolic blood pressure is the arithmetic mean of the 3 trough sitting systolic blood pressure measurements.

Time Frame: Baseline and Week 24.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	291	289	290
Least Squares Mean (Standard Error) Units: mmHg	-20.63 (0.946)	-21.24 (0.949)	-12.22 (0.948)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented. Overall 0.05 level of significance for multiple comparisons controlled using stepwise testing procedure.
	Method	ANCOVA

	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-8.41
	Confidence Interval	(2-Sided) 95% -11.04 to -5.78
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented. Overall 0.05 level of significance for multiple comparisons controlled using stepwise testing procedure.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-9.03
	Confidence Interval	(2-Sided) 95% -11.66 to -6.39
	Estimation Comments	[Not specified]

2. Secondary Outcome

Title: Change From Baseline in Mean Trough Clinic Sitting Diastolic Blood Pressure

Description: The change in mean trough clinic sitting diastolic blood pressure measured at final visit or week 24 relative to baseline. Diastolic blood pressure is the arithmetic mean of the 3 trough sitting diastolic blood pressure measurements.

Time Frame: Baseline and Week 24.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full analysis set with last observation carried forward.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	291	289	290
Least Squares Mean			

(Standard Error) Units: mmHg	-10.18 (0.553)	-10.54 (0.556)	-4.87 (0.555)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.31
	Confidence Interval	(2-Sided) 95% -6.85 to -3.78
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.66
	Confidence Interval	(2-Sided) 95% -7.21 to -4.12
	Estimation Comments	[Not specified]

3. Secondary Outcome

Title:	Change From Baseline in 24-hour Mean Systolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in 24-hour mean systolic blood pressure measured at week 24 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	131	135	127
Least Squares Mean (Standard Error) Units: mmHg	-12.65 (1.006)	-12.29 (0.992)	-7.83 (1.022)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.

	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-4.82
	Confidence Interval	(2-Sided) 95% -7.64 to -2.01
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.002
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-4.47
	Confidence Interval	(2-Sided) 95% -7.27 to -1.66
	Estimation Comments	[Not specified]

4. Secondary Outcome

Title: Change From Baseline in 24-hour Mean Diastolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.

Description: The change in 24-hour mean diastolic blood pressure measured at week 24 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 24.

Safety Issue? No

Outcome Measure Data

Analysis Population Description

Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	131	135	127

Least Squares Mean (Standard Error) Units: mmHg	-8.03 (0.655)	-8.32 (0.646)	-5.26 (0.666)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.003
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-2.77
	Confidence Interval	(2-Sided) 95% -4.61 to -0.94
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-3.06
	Confidence Interval	(2-Sided) 95% -4.89 to -1.24
	Estimation Comments	[Not specified]

5. Secondary Outcome

Title:	Change From Baseline in the 12-hour Mean Systolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring
Description:	The change in the 12-hour mean systolic blood pressure measured at week 24 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	131	135	127
Least Squares Mean (Standard Error) Units: mmHg	-12.06 (1.103)	-11.71 (1.087)	-8.28 (1.121)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.017
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate).

		Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-3.77
	Confidence Interval	(2-Sided) 95% -6.87 to -0.68
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.029
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-3.43
	Confidence Interval	(2-Sided) 95% -6.50 to -0.36
	Estimation Comments	[Not specified]

6. Secondary Outcome

Title:	Change From Baseline in the 12-hour Mean Diastolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring
Description:	The change in the 12-hour mean diastolic blood pressure measured at 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.

Number of Participants Analyzed	131	135	127
Least Squares Mean (Standard Error) Units: mmHg	-7.71 (0.743)	-8.07 (0.732)	-5.65 (0.755)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.052
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-2.06
	Confidence Interval	(2-Sided) 95% -4.15 to 0.02
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.022
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-2.42
	Confidence Interval	(2-Sided) 95% -4.49 to -0.35
	Estimation Comments	[Not specified]

7. Secondary Outcome

Title:	Change From Baseline in Daytime (6am to 10 pm) Mean Systolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in daytime (6am to 10pm) mean systolic blood pressure measured at week 24 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	131	135	127
Least Squares Mean (Standard Error) Units: mmHg	-12.61 (1.047)	-12.35 (1.032)	-8.08 (1.064)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of	**P-Value**	0.003

Hypothesis	**Comments**	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-4.53
	Confidence Interval	(2-Sided) 95% -7.46 to -1.59
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.004
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-4.26
	Confidence Interval	(2-Sided) 95% -7.18 to -1.35
	Estimation Comments	[Not specified]

8. Secondary Outcome

Title:	Change From Baseline in Daytime (6am to 10 pm) Mean Diastolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in daytime (6am to 10pm) mean diastolic blood pressure measured at 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10

	40 mg, tablets, orally, once daily for up to 22 weeks.	80 mg, tablets, orally, once daily for up to 22 weeks.	mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	131	135	127
Least Squares Mean (Standard Error) Units: mmHg	-8.19 (0.700)	-8.53 (0.689)	-5.55 (0.711)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.008
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-2.64
	Confidence Interval	(2-Sided) 95% -4.60 to -0.68
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.003
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-2.98
	Confidence Interval	(2-Sided) 95% -4.93 to -1.04
	Estimation Comments	[Not specified]

9. Secondary Outcome

Title:	Change From Baseline in the Nighttime (12 am to 6 am) Mean Systolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in nighttime (12am to 6am) mean systolic blood pressure measured at week 24 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	130	135	127
Least Squares Mean (Standard Error) Units: mmHg	-12.82 (1.135)	-12.69 (1.115)	-6.87 (1.147)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of	**P-Value**	<.001

Hypothesis	**Comments**	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.95
	Confidence Interval	(2-Sided) 95% -9.12 to -2.77
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.82
	Confidence Interval	(2-Sided) 95% -8.96 to -2.67
	Estimation Comments	[Not specified]

10. Secondary Outcome

Title:	Change From Baseline in the Nighttime (12 am to 6 am) Mean Diastolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in nighttime (12am to 6am) mean diastolic blood pressure measured at week 24 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 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10

	40 mg, tablets, orally, once daily for up to 22 weeks.	80 mg, tablets, orally, once daily for up to 22 weeks.	mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	130	135	127
Least Squares Mean (Standard Error) Units: mmHg	-7.44 (0.764)	-8.20 (0.750)	-4.43 (0.773)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	0.006
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-3.01
	Confidence Interval	(2-Sided) 95% -5.15 to -0.88
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority	No

	or Equivalence Analysis?	
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-3.77
	Confidence Interval	(2-Sided) 95% -5.89 to -1.65
	Estimation Comments	[Not specified]

11. Secondary Outcome

Title:	Change From Baseline in the Trough (22-24-hr) Mean Systolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in trough mean systolic blood pressure measured at week 24 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough mean is the average of all measurements recorded from 22 to 24 hours after dosing.
Time Frame:	Baseline and Week 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.
Number of Participants Analyzed	130	135	127
Least Squares Mean (Standard Error) Units: mmHg	-15.60 (1.172)	-14.93 (1.151)	-6.73 (1.186)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for

		treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-8.87
	Confidence Interval	(2-Sided) 95% -12.15 to -5.60
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-8.20
	Confidence Interval	(2-Sided) 95% -11.46 to -4.95
	Estimation Comments	[Not specified]

12. Secondary Outcome

Title:	Change From Baseline in the Trough (22-24-hr) Mean Diastolic Blood Pressure Measured by Ambulatory Blood Pressure Monitoring.
Description:	The change in trough mean diastolic blood pressure measured at week 24 relative to baseline. Ambulatory blood pressure monitoring measures blood pressure at regular intervals throughout the day and night. The trough mean is the average of all measurements recorded from 22 to 24 hours after dosing.
Time Frame:	Baseline and Week 24.
Safety Issue?	No

Outcome Measure Data

Analysis Population Description
Full Analysis Set.

Arm/Group Title	**Azilsartan Medoxomil 40 mg QD**	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
Arm/Group Description:	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily

	daily for up to 22 weeks.	daily for up to 22 weeks.	for up to 22 weeks.
Number of Participants Analyzed	130	135	127
Least Squares Mean (Standard Error) Units: mmHg	-10.21 (0.898)	-9.85 (0.883)	-4.53 (0.909)

Statistical Analysis 1

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 40 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.68
	Confidence Interval	(2-Sided) 95% -8.19 to -3.17
	Estimation Comments	[Not specified]

Statistical Analysis 2

Statistical Analysis Overview	**Comparison Groups**	Azilsartan Medoxomil 80 mg QD, Ramipril 10 mg QD
	Comments	[Not specified]
	Non-Inferiority	No

or Equivalence Analysis?		
	Comments	[Not specified]
Statistical Test of Hypothesis	**P-Value**	<.001
	Comments	Postbaseline P-value was from ANCOVA with terms for treatment (as a factor) and baseline value (as a covariate). Unadjusted p-value presented.
	Method	ANCOVA
	Comments	[Not specified]
Method of Estimation	**Estimation Parameter**	Mean Difference (Final Values)
	Estimated Value	-5.32
	Confidence Interval	(2-Sided) 95% -7.81 to -2.82
	Estimation Comments	[Not specified]

Adverse Events

Time Frame	Treatment-emergent adverse events are adverse events that started 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 (11.1)
Assessment Type	Systematic Assessment

Arm/Group Title	Azilsartan Medoxomil 40 mg QD	Azilsartan Medoxomil 80 mg QD	Ramipril 10 mg QD
Arm/Group Description	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 40 mg, tablets, orally, once daily for up to 22 weeks.	Azilsartan medoxomil 20 mg, tablets, orally, once daily for two weeks; then increased to 80 mg, tablets, orally, once daily for up to 22 weeks.	Ramipril 2.5 mg, tablets, orally, once daily for two weeks; then increased to 10 mg, tablets, orally, once daily for up to 22 weeks.

Serious Adverse Events

	Azilsartan Medoxomil 40 mg QD	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	8/294 (2.72%)	12/293 (4.1%)	6/293 (2.05%)
Cardiac disorders			
Acute coronary syndrome † A	0/294 (0%)	0/293 (0%)	1/293 (0.34%)
Angina pectoris † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Atrial fibrillation † A	1/294 (0.34%)	2/293 (0.68%)	1/293 (0.34%)
Congenital, familial and genetic disorders			
Hydrocele † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Eye disorders			
Cataract † A	1/294 (0.34%)	0/293 (0%)	0/293 (0%)
Retinal detachment † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Gastrointestinal disorders			
Salivary gland calculus † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Infections and infestations			
Appendicitis † A	1/294 (0.34%)	0/293 (0%)	1/293 (0.34%)
Hepatitis C † A	1/294 (0.34%)	0/293 (0%)	1/293 (0.34%)

Upper respiratory tract infection † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Urosepsis † A	1/294 (0.34%)	0/293 (0%)	1/293 (0.34%)
Injury, poisoning and procedural complications			
Ankle fracture † A	1/294 (0.34%)	0/293 (0%)	0/293 (0%)
Fall † A	0/294 (0%)	0/293 (0%)	1/293 (0.34%)
Road traffic accident † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Metabolism and nutrition disorders			
Hyperkalaemia † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant † A	1/294 (0.34%)	0/293 (0%)	0/293 (0%)
Renal cancer † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Nervous system disorders			
Cerebral ischaemia † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Epilepsy † A	0/294 (0%)	0/293 (0%)	1/293 (0.34%)
Grand mal convulsion † A	1/294 (0.34%)	0/293 (0%)	0/293 (0%)
Ischaemic stroke † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Syncope † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)
Respiratory, thoracic and mediastinal disorders			
Laryngeal oedema † A	0/294 (0%)	1/293 (0.34%)	0/293 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%		
	Azilsartan Medoxomil 40 mg QD	**Azilsartan Medoxomil 80 mg QD**	**Ramipril 10 mg QD**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	22/294 (7.48%)	16/293 (5.46%)	36/293 (12.29%)
Infections and infestations			
Nasopharyngitis † A	19/294 (6.46%)	13/293 (4.44%)	17/293 (5.8%)
Respiratory, thoracic and mediastinal disorders			
Cough † A	3/294 (1.02%)	4/293 (1.37%)	24/293 (8.19%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

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.

No publication related to study results will be published prior to publication of a multi-center report submitted for publication within 18 months after conclusion or termination of a study at all study sites. Results publications will be

submitted to sponsor for review 60 days in advance of publication. Sponsor can require removal of confidential information unrelated to study results. Sponsor can embargo a proposed publication for another 60 days to preserve intellectual property.

Results Point of Contact

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