Trial record **1 of 1** for: spd426-406

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Tilt-Table Study of the Clinical Efficacy of Midodrine in Symptomatic Orthostatic Hypotension

ClinicalTrials.gov Identifier: NCT01518946

Recruitment Status : Completed
First Posted : January 26, 2012
Results First Posted : July 31, 2014
Last Update Posted : January 9, 2019

Sponsor:
Shire

Information provided by (Responsible Party):
Shire

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Crossover Assignment; Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition	Orthostatic Hypotension
Interventions	Drug: Midodrine HCl Drug: Placebo

Enrollment	24

Participant Flow

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Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Midodrine HCl (Open-label Phase)	Placebo First, Then Midodrine HCl (Randomized Phase)	Midodrine HCl First, Then Placebo (Randomized Phase)
Arm/Group Description	On the morning of Day -1, subjects took their usual morning dose of midodrine HCl, using their own midodrine HCl supplies at approximately the same time before rising that they would normally take their morning dose. On the morning of Day 1, subjects had their usual morning dose of midodrine HCl withheld.	Placebo for first intervention on Day 2, then Midodrine hydrochloride dose at the subject's current dose level for the second intervention on Day 3.	Midodrine hydrochloride dose at the subject's current dose level for the first intervention Day 2, then placebo for second intervention on Day 3.
Period Title: **Open-label Phase**			
Started	24	0	0
Completed	20	0	0
Not Completed	4	0	0
Reason Not Completed			
Not specified	4	0	0
Period Title: **Randomized Phase (First Intervention)**			
Started	0	10	10
Completed	0	9	10
Not Completed	0	1	0
Reason Not Completed			
Not specified	0	1	0
Period Title: **Randomized Phase (Second Intervention)**			

Started	0	9	10
Completed	0	9	10
Not Completed	0	0	0

Baseline Characteristics

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Arm/Group Title	Placebo First, Then Midodrine HCl (Randomized Phase)	Midodrine HCl First, Then Placebo (Randomized Phase)	Total
Arm/Group Description	Placebo for first intervention on Day 2, then Midodrine hydrochloride dose at the subject's current dose level for the second intervention on Day 3.	Midodrine hydrochloride dose at the subject's current dose level for the first intervention Day 2, then placebo for second intervention on Day 3.	Total of all reporting groups
Overall Number of Baseline Participants	10	10	20
Baseline Analysis Population Description	Randomized Safety Analysis Set defined as all subjects who received at least 1 dose of randomized investigational product.		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years			
Number Analyzed	10 participants	10 participants	20 participants
	48.0 (19.52)	42.1 (18.64)	45.1 (18.82)
Age, Customized Measure Type: Number Unit of measure: Participants			
Number Analyzed	10 participants	10 participants	20 participants

18 to 65 years, inclusive		8	8	16
>= 66 years		2	2	4
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	10 participants	10 participants	20 participants
	Female	8 80.0%	10 100.0%	18 90.0%
	Male	2 20.0%	0 0.0%	2 10.0%
Region of Enrollment Measure Type: Number Unit of measure: Participants				
United States	Number Analyzed	10 participants	10 participants	20 participants
		10	10	20

Outcome Measures

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1. Primary Outcome

Title	Time to Onset of Syncope/Near Syncope While on Tilt Table
▼ Description	After a 30-minute supine period, the table was tilted from 0-90º within 30 seconds and maintained in that position for 45 minutes or until endpoint. Subjects were monitored for near-syncopal symptoms (subject felt sufficiently dizzy, lightheaded, faint, or felt like they were about to black out and requested the table to be returned to horizontal). Such a report ended the test. Alternatively, if the

	investigator observed that the subject was about to lose consciousness, that also constituted an endpoint.
Time Frame	1 hour post-dose

▼ Outcome Measure Data

▼ Analysis Population Description

The Full Analysis Set was defined as all randomized subjects who received at least 1 dose of randomized investigational product and who had at least 1 measurement of the time to onset of syncopal symptoms/near syncope during tilt-table testing.

Arm/Group Title	Placebo	Midodrine HCl
▼ Arm/Group Description:	single dose of matching placebo	dose at the subject's current dose level
Overall Number of Participants Analyzed	19	19
Least Squares Mean (Standard Error) Unit of Measure: seconds		
	1105.6 (186.82)	1626.6 (186.82)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Placebo, Midodrine HCl
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0131
	Comments	[Not Specified]
	Method	ANOVA
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	521.0
	Confidence Interval	(2-Sided) 95% 124.2 to 917.7
	Estimation Comments	[Not Specified]

Adverse Events

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Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Midodrine HCl (Open-label Phase)	Placebo (Randomized Phase)	Midodrine HCl (Randomized Phase)
Arm/Group Description	dose at the subject's current dose level	single dose of matching placebo	dose at the subject's current dose level

All-Cause Mortality

	Midodrine HCl (Open-label Phase)		Placebo (Randomized Phase)		Midodrine HCl (Randomized Phase)	
	Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--		--/--	

Serious Adverse Events

	Midodrine HCl (Open-label Phase)		Placebo (Randomized Phase)		Midodrine HCl (Randomized Phase)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	0/24 (0.00%)		0/20 (0.00%)		0/20 (0.00%)	

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	Midodrine HCl (Open-label Phase)		Placebo (Randomized Phase)		Midodrine HCl (Randomized Phase)	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	3/24 (12.50%)		1/20 (5.00%)		1/20 (5.00%)	
Gastrointestinal disorders						
Nausea	2/24 (8.33%)	2	0/20 (0.00%)	0	0/20 (0.00%)	0

General disorders						
Fatigue	0/24 (0.00%)	0	0/20 (0.00%)	0	1/20 (5.00%)	1
Musculoskeletal and connective tissue disorders						
Back Pain	0/24 (0.00%)	0	1/20 (5.00%)	1	0/20 (0.00%)	0
Nervous system disorders						
Headache	2/24 (8.33%)	2	0/20 (0.00%)	0	0/20 (0.00%)	0
Vascular disorders						
Flushing	0/24 (0.00%)	0	0/20 (0.00%)	0	1/20 (5.00%)	1
Hot Flush	0/24 (0.00%)	0	0/20 (0.00%)	0	1/20 (5.00%)	1

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

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

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

If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after Sponsor confirms there shall be no multicenter Study publication, the Institution and/or such Principal Investigator may publish the results from the Institution site individually.

Results Point of Contact

Name/Title: Study Physician
Organization: Shire
Phone: +1 866-842-5335

Publications of Results:

Smith W, Wan H, Much D, Robinson AG, Martin P. Clinical benefit of midodrine hydrochloride in symptomatic orthostatic hypotension: a phase 4, double-blind, placebo-controlled, randomized,

tilt-table study. Clin Auton Res. 2016 Aug;26(4):269-77. doi: 10.1007/s10286-016-0363-9. Epub 2016 Jul 2.

Responsible Party:	Shire
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