Trial record **1 of 1** for: HMFQ

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Study on the Tolerability of Duloxetine in Depressed Patients With Parkinson's Disease

ClinicalTrials.gov Identifier: NCT00437125

Recruitment Status : Completed
First Posted : February 19, 2007
Results First Posted : August 16, 2010
Last Update Posted : September 8, 2010

Sponsor:
Eli Lilly and Company

Information provided by:
Eli Lilly and Company

Study Type	Interventional
Study Design	Allocation: N/A; Intervention Model: Single Group Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Conditions	Major Depressive Disorder Idiopathic Parkinson Disease
Intervention	Drug: Duloxetine hydrochloride
Enrollment	151

Participant Flow

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Recruitment Details	
Pre-assignment Details	167 participants were screened and 16 participants were screen failures

Arm/Group Title	Duloxetine
Arm/Group Description	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Period Title: **Overall Study**	
Started	151
Completed	119
Not Completed	32
Reason Not Completed	
Adverse Event	12
Death	1
Clinical Relapse	1
Lack of Efficacy	1
Lost to Follow-up	1
Withdrawal by Subject	13

Withdrawal by Caregiver	2
Physician Decision	1

Baseline Characteristics

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Arm/Group Title		Duloxetine	
Arm/Group Description		Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks	
Overall Number of Baseline Participants		151	
Baseline Analysis Population Description		[Not Specified]	
Age Continuous Mean (Standard Deviation) Unit of measure: Years			
	Number Analyzed	151 participants	
		63.6 (8.9)	
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
	Number Analyzed	151 participants	
	Female	85	56.3%
	Male	66	43.7%
Race/Ethnicity, Customized Measure Type: Number Unit of measure: Participants			
Caucasian		151 participants	

	Number Analyzed	
		151
Region of Enrollment Measure Type: Number Unit of measure: Participants		
Italy	Number Analyzed	151 participants
		151
Current alcohol consumption by participants Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		130
yes		21
Current use of tobacco products by participants Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		140
yes		11
Depression in a distant relative of the participant Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		120
yes		1
unknown		30
		151 participants

Depression in a second degree relative of the participant Measure Type: Number Unit of measure: Participants	Number Analyzed	
no		126
yes		25
Depression in mother or father of participant Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		149
yes		1
unknown		1
Depression in sibling or child of participant Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		150
yes		1
Disease stage of the modified Hoen and Yahr staging scale [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
unilateral disease		23
unilateral plus axial involvement		16
bilateral disease, without impairment of balance		63

mild to moderate bilateral disease		9
		[1] Measure Description: Stage 1: unilateral disease; stage 1.5: unilateral plus axial involvement; Stage 2: bilateral disease, without impairment of balance; Stage 2.5: mild bilateral disease with recovery on pull test; Stage 3: mild to moderate bilateral disease, some postural instability, physically independent; Stage 4: severe disability, still able to walk or stand unassisted; Stage 5: wheelchair or bedridden unless aided.
Other Axis 1 disorder in distant relative of participant [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		119
yes		32
		[1] Measure Description: Any axis 1 disorder except depressive disorder.
Other Axis 1 disorder in parents of participant [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		149
yes		1
unknown		1
		[1] Measure Description: Any axis 1 disorder except depressive disorder.
Other Axis 1 disorder in second degree relative of participant [1]	Number Analyzed	151 participants

Measure Type: Number Unit of measure: Participants		
no		127
yes		24
		[1] Measure Description: Any axis 1 disorder except depressive disorder.
Other Axis 1 disorder in sibling or child of participant [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		150
yes		1
		[1] Measure Description: Any axis 1 disorder except depressive disorder.
Presence of major depressive episode diagnosed with Mini International Neuropsychiatric Interview [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	151 participants
no		2
yes		149

		[1] Measure Description: The Mini International Neuropsychiatric Interview (MINI) is a standardized diagnostic interview based on Diagnostic and Statistical Manual of Mental Disorders version 4 (DSM-IV) criteria. It was developed as a more concise and easily administered alternative to the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID).
Mini Mental State Examination (MMSE) Total Score [1] Mean (Standard Deviation) Unit of measure: Units on a scale		
	Number Analyzed	151 participants
		28.3 (1.8)
		[1] Measure Description: The MMSE is used to screen cognitive functioning and provides measures of orientation, registration (immediate memory), memory, and language functioning. The score range is 0-30; normal: 25-30; mild impairment: 21-24; moderate impairment: 10-20; severe impairment: <10.

Outcome Measures

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1. Primary Outcome

Title	Number of Participants Reporting Serious Adverse Events or Other Adverse Events Leading Either to Discontinuation or to Death
Description	The results reported are the number of participants who discontinued the study as a result of an adverse event (serious or other) or death.
Time Frame	baseline through 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Measure Type: Number Unit of Measure: participants	
	13

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	[Not Specified]
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Method of Estimation	Estimation Parameter	Percentage
	Estimated Value	8.6
	Confidence Interval	(1-Sided) 95% 13.3
	Estimation Comments	[Not Specified]

2. Secondary Outcome

Title	Change From Baseline to 12 Weeks on the Unified Parkinson's Disease Rating Scale (UPDRS) Total Score
▼ Description	

	Rating tool to follow the longitudinal course of Parkinson's Disease. It is composed of Section I: Mentation, Behavior, and Mood; Section II: Activities of Daily Living; Section III: Motor Examination; Section IV: Complications of therapy. These are evaluated by interview. Some sections require that multiple grades be assigned to each extremity. Only Sections II and III were rated in this study. A total of 160 points are possible (52 in Section II and 108 in Section III), where 0 represents no disability and 160 indicates maximal grade of disability.
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants were included in the analysis population. Last observation carried forward analysis. Two participants were excluded from calculation of change as they had no post-baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline; n=151	32.0 (12.6)
change; n=149	-0.3 (6.1)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there

			would be no change on the total UDPRS score from baseline to 12-week endpoint.
		Type of Statistical Test	Superiority or Other
		Comments	[Not Specified]
	Statistical Test of Hypothesis	P-Value	0.5553
		Comments	p-value is for total UDPRS score - change. A priori threshold for p-values was 0.05.
		Method	t-test, 2 sided
		Comments	[Not Specified]

3. Secondary Outcome

Title	Change From Baseline to 12 Weeks on the UKU (Udvalg for Kliniske Undersogelser: Committee for Clinical Investigations) Side Effect Rating Scale
▼ Description	Clinician-rated scale, providing side effect ratings of psychopharmacological medications. 48 items, each item is rated on a 4-point scale (0=not present; 1=mild; 2=moderate; 3=severe). The test is divided in 6 subscales, total scores for each subscale are calculated based on a weighted secondary scoring system. Subscales: psychic (score range:0-30), neurological (score range:0-24), autonomic (score range:0-33), other (score range:0-75), global assesment by subject (score range:0-3), and global assessment by doctor (score range:0-3). Higher ratings indicate greater impairment.
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants were included in the analysis population. Last observation carried forward analysis. One participant was excluded as no data for UKU were

available and other participants were excluded as relevant due to absence of either baseline or post-baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Mean (Standard Deviation) Unit of Measure: units on a scale	
Psychic subscale, baseline; n=136	6.8 (4.6)
Psychic subscale, change; n=114	-3.5 (4.4)
Neurological subscale, baseline; n=132	4.2 (2.8)
Neurological subscale, change; n=112	-1.2 (1.9)
Autonomic subscale, baseline; n=132	1.9 (2.2)
Autonomic subscale, change; n=113	-0.6 (1.9)
Other subscale, baseline; n=49	0.9 (2.3)
Other subscale, baseline; n=35	0.2 (2.3)
	0.2 (0.5)

Global assessment by participant, baseline; n=150	
Global assessment by participant, change; n=129	0.1 (0.7)
Global assessment by doctor, baseline; n=150	0.1 (0.5)
Global assessment by doctor, change; n=129	0.1 (0.7)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the total psychic subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for psychic subscale. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	

		Tested was the null hypothesis that there would be no change on the total neurological subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for neurological subscale. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the total autonomic subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0014
	Comments	p-value is for autonomic subscale. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the total other subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.5586
	Comments	p-value is for other subscale. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 5

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the global assessment by paticipant subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0848
	Comments	p-value is for global assessment by paticipant. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided

	Comments	[Not Specified]

▼ Statistical Analysis 6

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the global assessment by doctor subscale score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0263
	Comments	p-value is for global assessment by doctor. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

4. Secondary Outcome

Title	Change From Baseline on the Pittsburgh Sleep Quality Index (PSQI)
▼ Description	Self-rated questionnaire which assesses sleep quality and disturbances over a 1-month time interval. 19 individual items generate seven "component" scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The subject self-rates each of these seven areas of sleep. Scoring of answers is based on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert Scale. The total score is the sum of the 7 component scores (total score range: 0-21).
Time Frame	baseline, 4 weeks, 8 weeks, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants with baseline and post-baseline data for >= 1 visit for >= 1 efficacy variable were included in the analyses (Full Analysis Set population). Last observation carried forward analysis. Excluded 2 participants (no baseline measure of PSQI) and 13 participants from calculation of change (absence of any post-baseline measure).

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline, n=147	8.6 (3.7)
4 weeks change, n=134	-2.8 (3.1)
8 weeks change, n=134	-3.3 (3.5)
12 weeks change, n=134	-3.2 (3.5)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the Pittsburgh Sleep Quality

		Index from baseline to 4-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for 4 weeks change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the Pittsburgh Sleep Quality Index from baseline to 8-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for 8 weeks change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the Pittsburgh Sleep Quality

		Index from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for 12 weeks change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

5. Secondary Outcome

Title	Change From Baseline to 12 Weeks on the 17-item Hamilton Depression Rating Scale (HAMD-17) Total Score
▼ Description	The 17-item HAMD measures depression severity. Each item was evaluated and scored using either a 5-point scale (e.g. absent, mild, moderate, severe, very severe) or a 3-point scale (e.g. absent, mild, marked). The total score of HAMD-17 may range from 0 (normal) to 52 (severe).
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149

Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline	19.2 (3.5)
change	-10.1 (6.5)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the HAMD-17 total score from baseline to 12-week endpoint.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for the HAMD-17 total score. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

6. Secondary Outcome

Title	Change From Baseline to 12 Weeks on the Clinical Global Impression-Severity Scale
▼ Description	Measures severity of illness at the time of assessment compared with start of treatment. Scores range from 1 (normal, not at all ill) to 7 (among the most extremely ill patients).
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline	4.0 (0.7)
change	-1.5 (1.3)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change on the Clinical Global Impression-Severity scale score from baseline to end of week 12 of treatment.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for Clinical Global Impression-Severity scale - change. A priori

	threshold for p-values was 0.05.
Method	t-test, 2 sided
Comments	[Not Specified]

7. Secondary Outcome

Title	Patient's Global Impression-Improvement at Week 12
▼ Description	A scale that measures the patient's perception of improvement at the time of assessment compared with the start of treatment. Scoring: 1=very much better; 2=much better; 3=low better; 4=no change; 5=low worse; 6=much worse; 7=very much worse.
Time Frame	12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Measure Type: Number Unit of Measure: participants	
score=1	5
score=2	63
score=3	38
score=4	10

score=5	3
score=6	0
score=7	0

8. Secondary Outcome

Title	Change From Baseline to 12 Weeks in Beck Depression Inventory (BDI) Total Score
▼ Description	A 21-item, patient-completed questionnaire to assess characteristics of depression. Each of the 21 items corresponding to a symptom of depression is summed to give a single score. There is a four-point scale for each item ranging from 0 to 3. Total score of 0-13 is considered minimal range, 14-19 is mild, 20-28 is moderate, and 29-63 is severe.
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis. 27 participants had no post baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline, n=149	21.6 (6.1)
change, n=122	-12.0 (7.8)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no difference between baseline and post-baseline in BDI scores
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for BDI score - change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

9. Secondary Outcome

Title	Change From Baseline to 12 Weeks in Visual Analog Scale (VAS)
▼ Description	VAS for pain consists of 6 questions that assess overall pain, headache, back pain, shoulder pain, pain interference with daily activities, and pain while awake. Participant rates pain on a 100 millimeter (mm) line between two anchors (0= no pain and 100=very severe pain). Here, the line was only 93 mm long due to an error on the clinical research form and scores were adjusted to 0 to 93.
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least 1 efficacy variable were available (Full analysis set population) were

included in the analyses. Last observation carried forward analysis. Excluded were 2 participants with only post-baseline data and 1 participant with only baseline data.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Mean (Standard Deviation) Unit of Measure: units on a scale	
Overall pain, baseline; n=147	30.5 (24.1)
Overall pain, change; n=146	-5.1 (20.1)
Headaches, baseline; n=147	15.9 (20.3)
Headaches, change; n=146	-5.4 (17.1)
Back ache, baseline; n=147	34.9 (27.2)
Back ache, change; n=146	-10.2 (20.8)
Shoulder pain, baseline; n=147	26.7 (27.1)
Shoulder pain, change; n=146	-10.3 (22.1)
Interference, baseline; n=147	30.4 (26.8)
Interference, change; n=146	-8.2 (22.3)
	31.7 (25.9)

Pain while awake, baseline; n=147	
Pain while awake, change; n=146	-9.9 (21.8)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS overall pain scores.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0027
	Comments	p-value is for VAS overall pain score - change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS headaches scores.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	0.0002
	Comments	p-value is for VAS Headaches score -

		change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS back ache scores.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for VAS back ache score - change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS shoulder pain score.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for VAS shoulder pain score -

		change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 5

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS interference score.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for VAS interference score - change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

▼ Statistical Analysis 6

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in VAS pain while awake score.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	

			p-value is for VAS pain while awake score - change. A priori threshold for p-values was 0.05.
		Method	t-test, 2 sided
		Comments	[Not Specified]

10. Secondary Outcome

Title	Change From Baseline to 12 Weeks in Parkinson Disease Questionnaire - 39 Item Version (PDQ-39) Total Score
▼ Description	The PDQ-39 has 39 items. Higher scores reflect lower quality of life. The PDQ-39 has eight subscales: mobility (10 items), activities of daily living (six items), emotional wellbeing (six items), stigma (four items), social support (three items), cognition (four items), communication (three items), and bodily discomfort (three items). Items in each subscale, as well in the total scale, can be summarized into an index and transformed linearly to a 0-100 scale.
Time Frame	baseline, 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants with both baseline data and post-baseline data for at least 1 visit for at least 1 efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis. Excluded were 2 participants with no baseline measure and 29 participants with no post baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149

Mean (Standard Deviation) Unit of Measure: units on a scale	
baseline; n=147	32.9 (12.5)
change; n=118	-7.7 (9.9)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Duloxetine
	Comments	Tested was the null hypothesis that there would be no change from baseline to 12 weeks in PDQ-39 total score.
	Type of Statistical Test	Superiority or Other
	Comments	[Not Specified]
Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	p-value is for PDQ-39 total score - change. A priori threshold for p-values was 0.05.
	Method	t-test, 2 sided
	Comments	[Not Specified]

11. Secondary Outcome

Title	Average Change From Baseline to 12 Weeks in Blood Pressure
▼ Description	For each participant, changes across individual visits were averaged to obtain 1 measurement per participant.
Time Frame	baseline through 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description

All treated participants were included in the analysis population. 5 participants for standing measurement and 6 participants for supine measurements were excluded from calculation of change as they had either no baseline or no post-baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Mean (95% Confidence Interval) Unit of Measure: millimeter mercury	
systolic blood pressure, standing; n=146	-0.17 (-1.49 to 1.14)
diastolic blood pressure, standing; n=146	0.12 (-0.89 to 1.13)
systolic blood pressure, supine; n=145	-0.30 (-1.73 to 1.13)
diastolic blood pressure, supine; n=145	-0.45 (-1.48 to 0.58)

12. Secondary Outcome

Title	Average Change From Baseline to 12 Weeks in Heart Rate
▼ Description	For each participant, changes across individual visits were averaged to obtain 1 measurement per participant.
Time Frame	baseline through 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants were included in the analysis population. 6 participants were excluded from calculation of change as they had either no baseline or post-baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Mean (95% Confidence Interval) Unit of Measure: beats per minute	
standing, n=145	1.61 (0.71 to 2.51)
supine, n=145	1.16 (0.35 to 1.97)

13. Secondary Outcome

Title	Number of Participants With Abnormal Electrocardiograms (ECG) During the 12 Week Study
▼ Description	Included were participants with normal ECG at baseline who developed abnormal ECGs during the study.
Time Frame	baseline through 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants were included in the analysis population. 54 participants were excluded from calculation of change as they had abnormal ECG at baseline, no baseline measure, or no post-baseline measure.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	151
Measure Type: Number Unit of Measure: participants	
	3

14. Secondary Outcome

Title	Laboratory Analytes
▼ Description	Laboratory analytes were collected to assess adverse events which are listed in the reported adverse events section.
Time Frame	baseline through 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All enrolled participants for whom both baseline data and post-baseline data were available were included in the analyses.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	0

No data displayed because Outcome Measure has zero total analyzed.

15. Secondary Outcome

Title	Number of Participants Who Responded to Treatment by 12 Weeks
▼ Description	Response was defined as a >= 50% reduction in 17-item Hamilton Depression rating scale (HAMD) scores. The 17-item HAMD measures depression severity. Each item was evaluated and scored using either a 5-point scale (e.g. absent, mild, moderate, severe, very severe) or a 3-point scale (e.g. absent, mild, marked). The total score of HAMD-17 may range from 0 (normal) to 52 (severe).
Time Frame	12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Measure Type: Number Unit of Measure: participants	
	90

16. Secondary Outcome

Title	Number of Participants Who Reached Remission by 12 Weeks
▼ Description	Remission was defined as reaching a 17-item Hamilton Depression Rating Scale (HAMD) total score <=7. The 17-item HAMD measures depression severity. Each item was evaluated

	and scored using either a 5-point scale (e.g. absent, mild, moderate, severe, very severe) or a 3-point scale (e.g. absent, mild, marked). The total score of HAMD-17 may range from 0 (normal) to 52 (severe).
Time Frame	12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
All treated participants for whom both baseline data and post-baseline data for at least 1 visit for at least one efficacy variable were available (Full analysis set population) were included in the analyses. Last observation carried forward analysis.

Arm/Group Title	Duloxetine
▼ Arm/Group Description:	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1 week, followed by duloxetine 60 mg orally QD for 11 weeks
Overall Number of Participants Analyzed	149
Measure Type: Number Unit of Measure: participants	
	68

Adverse Events

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

Arm/Group Title	Duloxetine
▼ Arm/Group Description	Participants received duloxetine 30 milligram (mg) orally once daily (QD) for 1

	week, followed by duloxetine 60 mg orally QD for 11 weeks

All-Cause Mortality

	Duloxetine	
	Affected / at Risk (%)	
Total	--/--	

Serious Adverse Events

	Duloxetine	
	Affected / at Risk (%)	# Events
Total	3/151 (1.99%)	
Cardiac disorders		
Atrial fibrillation † 1	1/151 (0.66%)	1
Infections and infestations		
Pneumonia † 1	1/151 (0.66%)	1
Sepsis † 1 [1]	1/151 (0.66%)	1
Musculoskeletal and connective tissue disorders		
Myopathy † 1	1/151 (0.66%)	1
Nervous system disorders		
Cerebral haemorrhage † 1 [2]	1/151 (0.66%)	1
Renal and urinary disorders		
Renal failure acute † 1	1/151 (0.66%)	1
Urinary retention † 1	1/151 (0.66%)	1
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism † 1	1/151 (0.66%)	1
Skin and subcutaneous tissue disorders		
Decubitus ulcer † 1	1/151 (0.66%)	1

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

[1] This event resulted in death.

[2]

This event resulted in death after completing the 12 week study period but within 30 days after completing the study.

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	1%	
	Duloxetine	
	Affected / at Risk (%)	# Events
Total	39/151 (25.83%)	
Ear and labyrinth disorders		
Vertigo †1	2/151 (1.32%)	2
Gastrointestinal disorders		
Aptyalism †1	3/151 (1.99%)	3
Constipation †1	5/151 (3.31%)	5
Diarrhoea †1	2/151 (1.32%)	2
Nausea †1	6/151 (3.97%)	6
General disorders		
Asthenia †1	3/151 (1.99%)	3
Metabolism and nutrition disorders		
Hypercholesterolaemia †1	3/151 (1.99%)	3
Nervous system disorders		
Headache †1	3/151 (1.99%)	3
Somnolence †1	3/151 (1.99%)	3
Tremor †1	2/151 (1.32%)	2
Psychiatric disorders		
Agitation †1	2/151 (1.32%)	2
Anxiety †1	2/151 (1.32%)	2
Psychotic disorder †1	2/151 (1.32%)	2
Skin and subcutaneous tissue disorders		
Hyperhidrosis †1	2/151 (1.32%)	2

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.0

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.

Results Point of Contact

Name/Title:	Chief Medical Officer
Organization:	Eli Lilly and Company
Phone:	800-545-5979

Responsible Party:	Chief Medical Officer, Eli Lilly
ClinicalTrials.gov Identifier:	NCT00437125 History of Changes
Other Study ID Numbers:	11127
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