Trial record **1 of 1** for: F1J-CR-HMGM

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A Study of Patients With Major Depressive Disorder and Residual Apathy

ClinicalTrials.gov Identifier: NCT00985504

Recruitment Status : Completed
First Posted : September 28, 2009
Results First Posted : October 3, 2011
Last Update Posted : December 13, 2011

Sponsor:
Eli Lilly and Company

Collaborator:
Boehringer Ingelheim

Information provided by (Responsible Party):
Eli Lilly and Company

Study Details | Tabular View | Study Results | Disclaimer

How to Read a Study Record

Study Type:	Interventional

Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Triple (Participant, Care Provider, Investigator); Primary Purpose: Treatment
Condition:	Major Depressive Disorder
Interventions:	Drug: Duloxetine Drug: Escitalopram

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Acute treatment period (1 week): Participants randomized to switch to 60 milligrams (mg) duloxetine once daily (QD) by mouth (po) or 10 mg escitalopram QD po. Optimization period (7 weeks): Participants given duloxetine or escitalopram in acute study period may optimize their QD po doses (60-120 mg duloxetine QD po; 10-20 mg escitalopram QD po).

Reporting Groups

	Description
Duloxetine	Participants received 60 milligrams (mg) of duloxetine once daily (QD) by mouth (po) for 1 week (Acute Treatment Period) followed by 60-120 mg QD po for the remaining 7 weeks (Optimization Period), with an option to continue treatment for an additional 2 weeks.
Escitalopram	

	Participants received 10 mg of escitalopram QD po for 1 week (Acute Treatment Period) followed by 10-20 mg QD po for the remaining 7 weeks (Optimization Period), with an option to continue treatment for an additional 2 weeks.

Participant Flow for 2 periods

Period 1: Acute Treatment Period

	Duloxetine	Escitalopram
STARTED	244	239
COMPLETED	229	227
NOT COMPLETED	15	12
Adverse Event	3	4
Entry Criteria Not Met	1	2
Protocol Violation	2	0
Sponsor Decision	0	1
Withdrawal by Subject	9	5

Period 2: Optimization Period

	Duloxetine	Escitalopram
STARTED	229	227
COMPLETED	203	204
NOT COMPLETED	26	23
Adverse Event	7	9
Death	0	1
Lack of Efficacy	5	3
Lost to Follow-up	0	1
Physician Decision	1	0
Protocol Violation	3	1
Withdrawal by Subject	10	8

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Duloxetine	Participants received 60 milligrams (mg) of duloxetine once daily (QD) by mouth (po) for 1 week (Acute Treatment Period) followed by 60-120 mg QD po for the remaining 7 weeks (Optimization Period), with an option to continue treatment for an additional 2 weeks.
Escitalopram	Participants received 10 mg of escitalopram QD po for 1 week (Acute Treatment Period) followed by 10-20 mg QD po for the remaining 7 weeks (Optimization Period), with an option to continue treatment for an additional 2 weeks.
Total	Total of all reporting groups

Baseline Measures

	Duloxetine	**Escitalopram**	**Total**
Overall Participants Analyzed [Units: Participants]	**244**	**239**	**483**
Age [Units: Years] Mean (Standard Deviation)	**44.15 (13.81)**	**44.93 (12.89)**	**44.54 (13.35)**
Gender [Units: Participants]			
Female	**187**	**179**	**366**
Male	**57**	**60**	**117**

Ethnicity (NIH/OMB) [Units: Participants]			
Hispanic or Latino	**45**	**44**	**89**
Not Hispanic or Latino	**199**	**195**	**394**
Unknown or Not Reported	**0**	**0**	**0**
Race (NIH/OMB) [1] [Units: Participants]			
American Indian or Alaska Native	**34**	**37**	**71**
Asian	**90**	**82**	**172**
Native Hawaiian or Other Pacific Islander	**1**	**0**	**1**
Black or African American	**0**	**1**	**1**
White	**120**	**119**	**239**
More than one race	**1**	**0**	**1**
Unknown or Not Reported	**0**	**0**	**0**
[1] One participant selected 2 races. Therefore, the total number of participants in the race category will be larger than the number of participants in the baseline table.			
Region of Enrollment [Units: Participants]			
Australia	**24**	**25**	**49**
Canada	**44**	**43**	**87**
China	**47**	**41**	**88**
Italy	**23**	**22**	**45**
Korea, Republic of	**18**	**15**	**33**
Mexico	**42**	**43**	**85**
Russian Federation	**23**	**25**	**48**
Taiwan	**23**	**25**	**48**
Taking Escitalopram 3 Months Prior to Study Entry [1] [Units: Participants]			
Yes	**67**	**59**	**126**

No	**177**	**180**	**357**
[1] Previous therapy status is defined as the number of participants who had taken escitalopram 3 months prior to study entry.			
Apathy Evaluation Scale - Clinician Rated Version (AES-C) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**46.28 (7.82)**	**46.34 (8.14)**	**46.31 (7.97)**
[1] The AES-C is a validated 18-item instrument used to assess cognitive, behavioral, emotional and other symptoms of apathy. Clinicians rate each item based on verbal and nonverbal information provided by the participant. Item scores range from 1 (not at all characteristic) to 4 (a lot characteristic). Total scores range from 18 to 72 where higher derived scores indicate more severe apathy.			
Montgomery-Asberg Depression Rating Scale (MADRS) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**10.57 (3.49)**	**10.29 (3.68)**	**10.43 (3.59)**
[1] The MADRS is a rating scale for severity of depressive mood symptoms. The MADRS has a 10-item checklist. Items are rated on a scale of 0-6, for a total score range of 0 (low severity of depressive symptoms) to 60 (high severity of depressive symptoms).			
Montgomery-Asberg Depression Rating Scale (MADRS) Item 8 Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**1.82 (1.10)**	**1.82 (1.15)**	**1.82 (1.13)**
[1] The MADRS Item 8 assesses participants' inability to feel, through evaluation of their interest in their surroundings or activities that normally give pleasure, as well as their ability to react with adequate emotion to circumstances or people. The score ranges from 0 (normal interest in the surroundings and in other people) to 6 (the experience of being emotionally paralyzed, inability to feel anger, grief or pleasure and a complete or even painful failure to feel for close relatives and friends).			
Clinical Global Impressions of Severity Scale (CGI-S) [1]	**3.05 (0.91)**	**3.04 (0.91)**	**3.05 (0.91)**

[Units: Units on a scale] Mean (Standard Deviation)			

[1] The CGI-S 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 participants).

Rothschild Scale for Antidepressant Tachyphylaxis (RSAT) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**10.72 (4.92)**	**10.51 (4.95)**	**10.62 (4.93)**

[1] RSAT assesses symptoms of apathy or decreased motivation among depressed participants who have achieved symptomatic remission with antidepressant treatment and consists of 6 self-report items assessing energy level, motivation and interest, cognitive functioning, weight gain, sleep and sexual functioning, as well as affect. Each item score ranges from 0 to 4 with total scores ranging from 0 to 28. Higher scores indicate greater disease severity.

The Massachusetts General Hospital Cognitive and Physical functioning Questionnaire (MGH-CPFQ) Total [1] [Units: Units on a scale] Mean (Standard Deviation)	**24.78 (5.73)**	**24.69 (5.83)**	**24.73 (5.78)**

[1] The MGH-CPFQ is a 7-item participant-rated questionnaire evaluating the participant's cognitive and physical well-being during the past month. It assesses motivation, wakefulness, energy, focus, recall, word-finding difficulty, and mental acuity. Each of the 7 items is scored on a 6-point scale ranging from "greater than normal" (score of 1) to "normal" (score of 2), to "totally absent" (score of 6). Total scores range from 7 to 42. Higher scores indicate greater disease severity.

Sheehan Disability Scale - Total Score (SDS Total) [1] [Units: Units on a scale] Mean (Standard Deviation)	**15.32 (6.76)**	**14.62 (6.39)**	**14.98 (6.58)**

[1] The SDS is completed by the participant and is used to assess the effect of the participant's symptoms on their work/social/family life. Total scores range from 0 to 30 with higher values indicating greater disruption in the participant's work/social/family life.

Outcome Measures

Show All Outcome Measures

1. Primary: Change From Baseline in the Apathy Evaluation Scale - Clinician Rated Version (AES-C) Total Score at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 1

2. Secondary: Change From Baseline in the Apathy Evaluation Scale-Clinician Rated Version (AES-C) Subscale Scores at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 2

3. Secondary: Change From Baseline in the Rothschild Scale for Antidepressant Tachyphylaxis (RSAT) Total and Individual Item Scores at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 3

4. Secondary: Patient's Global Impressions of Improvement Scale (PGI-I) Rating Scale Score at Week 8 [Time Frame: 8 weeks]

   Show Outcome Measure 4

5. Secondary: Change From Baseline in the Clinical Global Impression of Severity (CGI-S) Rating Scale at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 5

6. Secondary: Change From Baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) Total Score and Item 8 (Inability to Feel) at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 6

7. Secondary: Change From Baseline in the Massachusetts General Hospital Cognitive and Physical Functioning Questionnaire (MGH-CPFQ) Total and Item Scores at Week 8 [Time Frame: Baseline, 8 weeks]

   Show Outcome Measure 7

8. **Secondary: Change From Baseline in the Sheehan Disability Scale (SDS) Total and Individual Scores at Week 8 [Time Frame: Baseline, 8 weeks]**

Show Outcome Measure 8

9. **Secondary: Percentage of Participants Who Relapsed During 8 Weeks [Time Frame: Baseline through 8 weeks]**

Show Outcome Measure 9

10. **Secondary: Number of Days From Baseline to Relapse as Defined by Montgomery-Asberg Depression Rating Scale (MADRS) Total Score ≥16 During 8 Weeks [Time Frame: Baseline through 8 weeks]**

Show Outcome Measure 10

11. **Secondary: Percentage of Participants Who Discontinue Due to Lack of Efficacy During 8 Weeks [Time Frame: Baseline through 8 weeks]**

Show Outcome Measure 11

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

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.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Responsible Party:	Eli Lilly and Company
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