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Trial record **1 of 1** for: F1J-EW-HMGD

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Early Versus Delayed Switch in Medication in Patients With Major Depressive Disorder

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ClinicalTrials.gov Identifier: NCT00810069

Recruitment Status : Completed
First Posted : December 17, 2008
Results First Posted : June 21, 2011
Last Update Posted : June 21, 2011

Sponsor:
Eli Lilly and Company

Information provided by:
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: Double (Participant, Investigator); Primary Purpose: Treatment
Condition:	Major Depressive Disorder
Interventions:	Drug: Duloxetine Hydrochloride 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
Participants showing improvement (≥30% baseline score reduction on the HAMD-17) during Period I did not continue to Period II of the study. Qualified participants for Period II were randomized to either Early Intervention Strategy Arm or Delayed Intervention Strategy Arm.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Baseline demographics and primary and secondary outcomes are reported only for Period II (Double Blind Treatment Strategy). Adverse events (AEs) are reported for Period I (Acute Escitalopram Treatment) and Period II.

Reporting Groups

	Description
Escitalopram (Acute Treatment)	Escitalopram 10 milligrams (mg) per day for 4 weeks
Early Intervention	Duloxetine flexible dose (60 or 120 milligrams [mg] daily) for 12 weeks
Delayed Intervention	Escitalopram flexible dose (10 to 20 milligrams [mg] daily) for 4 weeks. Then in participants with no-response, switch treatment to duloxetine flexible dose (60 or 120 mg daily)

	for 8 weeks. In participants with a response continue treatment with escitalopram (10 to 20 milligrams [mg] daily) for 8 weeks.

Participant Flow for 2 periods

Period 1: Lead-in Period I

	Escitalopram (Acute Treatment)	Early Intervention	Delayed Intervention
STARTED	840	0	0
COMPLETED	566	0	0
NOT COMPLETED	274	0	0
Adverse Event	43	0	0
Lack of Efficacy	1	0	0
Lost to Follow-up	19	0	0
Physician Decision	1	0	0
Protocol Violation	1	0	0
Withdrawal by Subject	46	0	0
Protocol entry criterion not met	5	0	0
Randomization criteria not met	158	0	0

Period 2: Double-Blind Period II

	Escitalopram (Acute Treatment)	Early Intervention	Delayed Intervention
STARTED	0	282	284 [1]
COMPLETED	0	226	212
NOT COMPLETED	0	56	72
Adverse Event	0	9	8
Lack of Efficacy	0	7	12
Lost to Follow-up	0	9	9
Physician Decision	0	0	1

Withdrawal by Subject	**0**	**21**	**35**
Protocol entry criterion not met	**0**	**0**	**1**
Clinical relapse	**0**	**3**	**0**
Protocol Violation	**0**	**7**	**6**

[1] At Week 8 - delayed intervention divided by response to treatment (nonresponders or responders).

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
Early Intervention	Duloxetine flexible dose (60 or 120 milligrams [mg] daily) for 12 weeks
Delayed Intervention	Escitalopram flexible dose (10 to 20 milligrams [mg] daily) for 4 weeks. Then in participants with no-response, switch treatment to duloxetine flexible dose (60 or 120 mg daily) for 8 weeks. In participants with a response continue treatment with escitalopram (10 to 20 milligrams [mg] daily) for 8 weeks.
Total	Total of all reporting groups

Baseline Measures

	Early Intervention	**Delayed Intervention**	**Total**

Overall Participants Analyzed [Units: Participants]	**282**	**284**	**566**
Age [Units: Years] Mean (Standard Deviation)	**48.3 (13.48)**	**47.4 (12.72)**	**47.9 (13.10)**
Gender [Units: Participants]			
Female	**196**	**197**	**393**
Male	**86**	**87**	**173**
Region of Enrollment [Units: Participants]			
France	**54**	**54**	**108**
Hungary	**6**	**6**	**12**
Slovenia	**6**	**4**	**10**
Greece	**10**	**10**	**20**
Spain	**71**	**73**	**144**
Turkey	**10**	**10**	**20**
Romania	**18**	**18**	**36**
Denmark	**12**	**14**	**26**
Netherlands	**5**	**4**	**9**
Italy	**19**	**20**	**39**
Sweden	**71**	**71**	**142**
Race [Units: Participants]			
Black or African American	**2**	**2**	**4**
White	**280**	**282**	**562**
Clinical Global Impression-Major Depressive Disorder-Severity (CGI-MDD-S) Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**4.6 (0.59)**	**4.6 (0.64)**	**4.6 (0.62)**

[1]

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.

Quick Inventory of Depressive Symptomatology-Self Reported (QIDS16SR) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**16.4 (3.82)**	**16.7 (3.43)**	**16.5 (3.63)**

[1] A 16-item participant-rated measure of depressive symptomatology. The total score ranges from 0 to 27 with higher scores indicative of greater severity.

17-item Hamilton Depression Rating Scale (HAMD-17) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**24.0 (3.57)**	**24.4 (3.83)**	**24.2 (3.70)**

[1] 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).

Visual Analog Scale (VAS) Overall Pain Severity [1] [Units: Units on a scale] Mean (Standard Deviation)	**3.6 (2.76)**	**3.8 (2.81)**	**3.7 (2.78)**

[1] 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 10 centimeter (cm) line between two anchors (0= no pain and 10=very severe pain).

Sheehan Disability Scale (SDS) Total Score [1] [Units: Units on a scale] Mean (Standard Deviation)	**19.9 (5.12)**	**19.9 (5.52)**	**19.9 (5.32)**

[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.

Euro Quality of Life-5 Dimensions Questionnaire (EQ-5D) Score [1] [Units: Units on a scale] Mean (Standard Deviation)			
EQ-5D UK Population-based Index Score	**0.40 (0.291)**	**0.34 (0.312)**	**0.37 (0.303)**
Health State Score	**4.23 (1.873)**	**3.86 (1.704)**	**4.05 (1.798)**
[1] EQ-5D: a generic, multidimensional, health-related, quality of life instrument. Participants rate health state in 5 domains: mobility, self-care, usual activities, pain/discomfort, mood. A single score between 1-3 is generated for each domain. Outcome rating on 5 domains is mapped to a single index through an algorithm. Index ranges between 0-1 with higher score indicating better health state perceived by participant. Health State Score: self-rated health on a vertical visual analogue scale measured in centimeters. Best imaginable health state=10 and worst imaginable health state=0.			
Number of work hours worked per week [Units: Hours] Mean (Standard Deviation)	**38.0 (8.30)**	**37.2 (9.53)**	**37.6 (8.94)**
Number of work hours missed in the last 4 weeks [1] [Units: Hours] Mean (Standard Deviation)	**86.9 (63.09)**	**87.5 (66.32)**	**87.2 (64.67)**
[1] Only those participants who missed at least 1 hour of work were included: 79 participants in the Early Intervention Strategy group and 93 participants in the Delayed Intervention Strategy group.			
Number of work hours missed due to depression in the last 4 weeks [1] [Units: Hours] Mean (Standard Deviation)	**88.8 (64.14)**	**88.5 (67.05)**	**88.6 (65.56)**
[1] Only those participants who missed at least 1 hour of work due to depression were included: 73 participants in the Early Intervention Strategy group and 90 participants in the Delayed Intervention Strategy group.			
Number of visits to primary healthcare provider due to	**1.6 (0.95)**	**1.8 (1.10)**	**1.7 (1.03)**

depression in the last 4 weeks [Units: Visits] Mean (Standard Deviation)			
Number of visits to emergency room or equivalent facility due to depression in the last 4 weeks [Units: Visits] Mean (Standard Deviation)	**1.1 (0.27)**	**1.1 (0.48)**	**1.1 (0.40)**
Number of visits to other specialists due to depression in the last 4 weeks [Units: Visits] Mean (Standard Deviation)	**2.0 (1.44)**	**1.6 (0.98)**	**1.8 (1.26)**
Has the participant been hospitalized due to depression in the last 4 weeks [Units: Participants]			
Yes	**4**	**5**	**9**
No	**277**	**278**	**555**
Unknown	**1**	**0**	**1**
Missing	**0**	**1**	**1**

Outcome Measures

Show All Outcome Measures

1. **Primary: Time to Confirmed Response by ≥ 50% Change From Baseline Reduction in the Hamilton Depression Rating Scale-17 Items (HAMD-17) [Time Frame: Week 4 through Week 16]**

   Show Outcome Measure 1

2. **Primary: Estimated Probability of Not Reaching Confirmed Response at 12 Weeks Based on the Survival Function for the Time to Confirmed Response [Time Frame: Week 4 through Week 16]**

   Show Outcome Measure 2

3. **Primary: Time to Confirmed Remission by a Hamilton Depression Rating Scale-17 Items (HAMD-17) Score of ≤ 7 That is Maintained for Two Consecutive Visits [Time Frame: Week 4 through Week 16]**

Show Outcome Measure 3

4. **Primary: Estimated Probability of Not Reaching Confirmed Remission at 12 Weeks Based on the Survival Function for the Time to Confirmed Remission [Time Frame: Week 4 through Week 16]**

Show Outcome Measure 4

5. **Secondary: Time to Confirmed Response as Defined by ≥ 50% Reduction From Baseline Reduction in the 16-Item Quick Inventory of Depressive Symptomatology Self Report (QIDS16SR) That is Reported for Two Consecutive Visits [Time Frame: Week 4 through Week 16]**

Show Outcome Measure 5

6. **Secondary: Time to Confirmed Remission as Defined by a 16-Item Quick Inventory of Depressive Symptomatology Self Report (QIDS16SR) Score of ≤ 5 That is Maintained for Two Consecutive Visits. [Time Frame: Week 4 through Week 16]**

Show Outcome Measure 6

7. **Secondary: Clinical Global Impressions of Severity (CGI-S) Scale [Time Frame: Baseline, Week 4, Week 6, Week 8, Week 10, Week 12, Week 14, Week 16]**

Show Outcome Measure 7

8. **Secondary: Visual Analog Scale (VAS) - Overall Pain Severity [Time Frame: Baseline, Week 4, Week 6, Week 8, Week 10, Week 12, Week 14, Week 16]**

Show Outcome Measure 8

9. **Secondary: Euro Quality of Life Questionnaire-5 Dimensions (EQ-5D) Scale - Health State Score [Time Frame: Baseline, Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 9

10. **Secondary:**

Euro Quality of Life Questionnaire-5 Dimensions (EQ-5D) Scale - United Kingdom (UK) Population Based Index Score [Time Frame: Baseline, Week 4, Week 8, Week 12, Week 16]

Show Outcome Measure 10

11. **Secondary: Sheehan Disability Scale (SDS) Normal Functioning Total Score [Time Frame: Baseline, Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 11

12. **Secondary: Resource Utilisation - Number of Hours Worked Per Week [Time Frame: Baseline, Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 12

13. **Secondary: Resource Utilisation - Number of Work Hours Missed in the Last 4 Weeks [Time Frame: Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 13

14. **Secondary: Resource Utilisation - Number of Work Hours Missed Due to Depression in the Last 4 Weeks [Time Frame: Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 14

15. **Secondary: Resource Utilisation - Number of Visits to Primary Healthcare Provider Due to Depression in the Last 4 Weeks [Time Frame: Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 15

16. **Secondary: Resource Utilisation - Number of Visits to Other Specialists Due to Depression in the Last 4 Weeks [Time Frame: Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 16

17. **Secondary: Resource Utilisation - Has the Participant Been Hospitalized Due to Depression in the Last 4 Weeks - Number of Participants With a Yes Response [Time Frame: Week 4, Week 8, Week 12, Week 16]**

Show Outcome Measure 17

18. Secondary: Number of Participants With Adverse Events (AEs) [Time Frame: Baseline through Week 16]

Show Outcome Measure 18

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:

Name/Title: Chief Medical Officer
Organization: Eli Lilly and Company
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Responsible Party:	Chief Medical Officer, Eli LIlly
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