Trial record **1 of 1** for: H6D-EW-LVIJ

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A Study in Patients With Erectile Dysfunction

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT01122264

Recruitment Status : Completed
First Posted : May 13, 2010
Results First Posted : October 19, 2012
Last Update Posted : October 19, 2012

Sponsor:
Eli Lilly and Company

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: None (Open Label); Primary Purpose: Treatment

Condition:	Erectile Dysfunction
Interventions:	Drug: Tadalafil Drug: Sildenafil Citrate

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
No text entered.

Reporting Groups

	Description
Tadalafil On Demand	Participants were instructed to take a 10-milligram (mg) or 20-mg tablet of tadalafil orally on demand, with a maximum of 4 tablets per week (and no more than 1 tablet per day) for 24 weeks.
Tadalafil Once a Day	Participants were instructed to take a 5-mg or 2.5-mg tablet of tadalafil orally once a day for 24 weeks.
Sildenafil Citrate On Demand	Participants were instructed to take a 50-mg, 100-mg, or 25-mg tablet of sildenafil citrate orally on demand, with a maximum of 4 tablets per week (and no more than 1 tablet per day) for 24 weeks.

Participant Flow: Overall Study

	Tadalafil On Demand	**Tadalafil Once a Day**	**Sildenafil Citrate On Demand**

STARTED	**252**	**257**	**261**
Received at Least 1 Dose of Study Drug	**250**	**257**	**260**
COMPLETED	**220**	**228**	**214**
NOT COMPLETED	**32**	**29**	**47**
Adverse Event	**6**	**5**	**7**
Death	**1**	**0**	**0**
Lost to Follow-up	**5**	**9**	**13**
Entry Criteria Not Met	**1**	**0**	**0**
Protocol Violation	**7**	**7**	**9**
Withdrawal by Subject	**6**	**6**	**16**
Physician Decision	**3**	**1**	**1**
Lack of Efficacy	**3**	**1**	**1**

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
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Sildenafil Citrate On Demand	Participants were instructed to take a 50-mg, 100-mg, or 25-mg tablet of sildenafil citrate orally on demand, with a maximum of 4 tablets per week (and no more than 1 tablet per day) for 24 weeks.
Total	Total of all reporting groups

Baseline Measures

	Tadalafil On Demand	Tadalafil Once a Day	Sildenafil Citrate On Demand	Total
Overall Participants Analyzed [Units: Participants]	**252**	**257**	**261**	**770**
Age [Units: Years] Mean (Standard Deviation)	**53.2 (11.57)**	**52.9 (11.69)**	**53.0 (11.76)**	**53.0 (11.66)**
Gender [Units: Participants]				
Female	**0**	**0**	**0**	**0**
Male	**252**	**257**	**261**	**770**
Race (NIH/OMB) [Units: Participants]				
American Indian or Alaska Native	**0**	**0**	**0**	**0**
Asian	**0**	**0**	**0**	**0**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**	**0**
Black or African American	**2**	**4**	**4**	**10**
White	**248**	**251**	**254**	**753**
More than one race	**0**	**0**	**1**	**1**

Unknown or Not Reported	**2**	**2**	**2**	**6**
Region of Enrollment [Units: Participants]				
Portugal	**6**	**5**	**7**	**18**
France	**99**	**102**	**100**	**301**
Greece	**9**	**8**	**9**	**26**
Poland	**15**	**16**	**16**	**47**
Spain	**48**	**49**	**52**	**149**
Romania	**20**	**22**	**21**	**63**
Germany	**45**	**45**	**47**	**137**
United Kingdom	**10**	**10**	**9**	**29**

Outcome Measures

Show All Outcome Measures

1. **Primary: Time to Discontinuation of Randomized Treatment [Time Frame: Baseline up to 334 days]**

   Show Outcome Measure 1

2. **Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the International Index of Erectile Function (IIEF) Erectile Function (EF) Domain [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

   Show Outcome Measure 2

3. **Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the International Index of Erectile Function (IIEF) Orgasmic Function Domain [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

   Show Outcome Measure 3

4. **Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the International Index of Erectile Function (IIEF) Sexual Desire Domain [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

Show Outcome Measure 4

5. Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the Sexual Encounter Profile (SEP) [Time Frame: Baseline, 4, 8, 16, and 24 weeks]

Show Outcome Measure 5

6. Secondary: Global Assessment Questions (GAQ) [Time Frame: 24 weeks]

Show Outcome Measure 6

7. Secondary: Number of Treatment Switches [Time Frame: Baseline through 24 weeks]

Show Outcome Measure 7

8. Secondary: Patterns of Erectile Dysfunction Treatment Change [Time Frame: Baseline through 24 weeks]

Show Outcome Measure 8

9. Secondary: Reasons for Discontinuation of Randomized Erectile Dysfunction Treatment [Time Frame: Baseline through 24 weeks]

Show Outcome Measure 9

10. Secondary: Number of Days From the 8-Week Study Visit to the Time the Participant Discontinues From All Phosphodiesterase Type 5 (PDE5) Inhibitor Treatments [Time Frame: 8 weeks up to 334 days]

Show Outcome Measure 10

11. Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the International Index of Erectile Function (IIEF) Intercourse Satisfaction Domain [Time Frame: Baseline, 4, 8, 16, and 24 weeks]

Show Outcome Measure 11

12. Secondary: Change From Baseline to 4, 8, 16 and 24 Weeks of the International Index of Erectile Function (IIEF) Overall Satisfaction Domain [Time Frame: Baseline, 4, 8, 16, and 24 weeks]

Show Outcome Measure 12

13. **Secondary: Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) Questionnaire at 4, 8, 16, and 24 Weeks [Time Frame: 4, 8, 16, and 24 weeks]**

Show Outcome Measure 13

14. **Secondary: Change From Baseline to 24 Week Endpoint of the Sexual Self-Confidence, Spontaneity, and Time Concerns Domains (23-items) of the Psychological and Interpersonal Relationships Scale (PAIRS) [Time Frame: Baseline, 24 weeks]**

Show Outcome Measure 14

15. **Secondary: Change From Baseline to 4, 8, 16, and 24 Weeks of the Sexual Relationship Domain of the Self-Esteem and Relationship (SEAR) Questionnaire [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

Show Outcome Measure 15

16. **Secondary: Change From Baseline to 4, 8, 16, and 24 Weeks of the Confidence Domain of the Self-Esteem and Relationship (SEAR) Questionnaire [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

Show Outcome Measure 16

17. **Secondary: Change From Baseline to 4, 8, 16, and 24 Weeks of the Self Esteem Domain of the Self-Esteem and Relationship (SEAR) Questionnaire [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

Show Outcome Measure 17

18. **Secondary: Change From Baseline to 4, 8, 16, and 24 Weeks of the Overall Relationship Domain of the Self-Esteem and Relationship (SEAR) Questionnaire [Time Frame: Baseline, 4, 8, 16, and 24 weeks]**

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
phone: 800-545-5979

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Buvat J, Büttner H, Hatzimouratidis K, Vendeira PA, Moncada I, Boehmer M, Henneges C, Boess FG. Adherence to initial PDE-5 inhibitor treatment: randomized open-label study comparing tadalafil once a day, tadalafil on demand, and sildenafil on demand in patients with erectile dysfunction. J Sex Med. 2013 Jun;10(6):1592-602. doi: 10.1111/jsm.12130. Epub 2013 Apr 2.

Responsible Party:	Eli Lilly and Company
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