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

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A Study of Tadalafil After Radical Prostatectomy (REACTT)

ClinicalTrials.gov Identifier: NCT01026818

Recruitment Status : Completed
First Posted : December 4, 2009
Results First Posted : November 14, 2013
Last Update Posted : January 14, 2014

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 Description

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Brief Summary:

The study will include patients with localized prostate cancer who experience erectile dysfunction following bilateral nerve-sparing radical prostatectomy. Patients will be randomly assigned to three treatment arms: Tadalafil 5 mg once a day, Tadalafil 20 mg on demand (prior to anticipated sexual activity), and placebo. Patients will stay on therapy for 9 months and after withdrawal of medication for 6 weeks, patients will be evaluated for recovery of unassisted erectile function (without medication). An open-label extension for three months will evaluate the responsiveness of all patients to Tadalafil 5 mg once a day. Further objectives are to evaluate the treatment satisfaction of the respective therapies.

Condition or disease	Intervention/treatment	Phase
Erectile Dysfunction	Drug: Tadalafil Drug: Placebo	Phase 4

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	583 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	A Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Effect on Unassisted Erectile Function of the Early Use of Tadalafil 5 mg Once a Day and Tadalafil 20 mg On Demand Treatment for 9 Months in Subjects Undergoing Bilateral Nerve-Sparing Radical Prostatectomy
Study Start Date :	November 2009
Primary Completion Date :	October 2012
Study Completion Date :	October 2012

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Erectile Dysfunction

Drug Information available for: Tadalafil

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Tadalafil daily [5 milligrams (mg)] After the treatment period and 6-week study Drug-Free Period, all participants can continue on study in an optional 5-mg tadalafil 3-month Open-Label Period.	Drug: Tadalafil Administered by mouth for 9 months Other Names: • Cialis • LY450190
Experimental: Tadalafil on demand (20 mg) After the treatment period and 6-week study Drug-Free Period, all participants can continue on study in an optional 5-mg tadalafil 3-month Open-Label Period.	Drug: Tadalafil Administered by mouth for 9 months Other Names: • Cialis • LY450190
Placebo Comparator: Placebo After the treatment period and 6-week study Drug-Free Period, all participants can continue on study in an optional 5-mg tadalafil 3-month Open-Label Period.	Drug: Placebo Administered by mouth, daily or on demand for 9 months

Outcome Measures

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Primary Outcome Measures :

1. Percentage of Participants With a Score of Greater Than or Equal to 22 in the Erectile Function (EF) Domain of the International Index of Erectile Function (IIEF) Questionnaire [Time Frame: Month 10.5]

   Self-reported erectile function during the past 4 weeks. IIEF- EF is the sum of Questions 1-5 and 15 of the IIEF. Questions 1-5 are scored 0 (no sexual activity for

Question 1, no sexual stimulation for Question 2 and did not attempt intercourse for Questions 3-5) to 5 (high erectile function) and Question 15 is scored 1 (very low confidence) to 5 (very high confidence), for a total score ranging from 1 to 30. Higher scores represent better erectile function. Data presented are the percentage of participants with an IIEF-EF Total Score greater than or equal to (≥) 22.

Secondary Outcome Measures :

1. Percentage of Participants With a Score of Greater Than or Equal to 22 in the International Index of Erectile Function- Erectile Function (IIEF-EF) Domain [Time Frame: Month 9 and Month 13.5]

   Self-reported erectile function during the past 4 weeks. IIEF- EF is the sum of Questions 1-5 and 15 of the IIEF. Questions 1-5 are scored 0 (no sexual activity for Question 1, no sexual stimulation for Question 2 and did not attempt intercourse for Questions 3-5) to 5 (high erectile function) and Question 15 is scored 1 (very low confidence) to 5 (very high confidence), for a total score ranging from 1 to 30. Higher scores represent better erectile function. Data presented are the percentage of participants with an IIEF-EF Total Score greater than or equal to (≥) 22.

2. Change From Baseline to Endpoint in the International Index of Erectile Function-Erectile Function (IIEF-EF) Total Score [Time Frame: Randomization (Baseline), Months 9 and 10.5 and 13.5]

   Self-reported erectile function during the past 4 weeks. IIEF- EF is the sum of Questions 1-5 and 15 of the IIEF. Questions 1-5 are scored 0 (no sexual activity for Question 1, no sexual stimulation for Question 2 and did not attempt intercourse for Questions 3-5) to 5 (high erectile function) and Question 15 is scored 1 (very low confidence) to 5 (very high confidence), for a total score ranging from 1 to 30. Higher scores represent better erectile function. The Mixed Model for Repeated Measures (MMRM) analysis was used to calculate Least Squares (LS) mean and 95% confidence interval (CI). LS mean values are adjusted for baseline score, treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

3. Change From Baseline to Endpoint in the International Index of Erectile Function (IIEF) Domains (Intercourse Satisfaction Domain, Orgasmic Function Domain, Sexual Desire

Domain, Overall Satisfaction Domain) [Time Frame: Randomization (Baseline), Months 9 and 10.5 and 13.5]

Self-reported overall satisfaction during past 4 weeks. Orgasmic function score is sum of Questions (Q)9 and 10 of IIEF. Scores range from 0 (no sexual stimulation or intercourse) to 5 (high orgasm) for each Q, total 0 to 10. Sexual desire score is sum of Q11 and 12 of IIEF. Scores range from 1 (low/no desire) to 5 (high desire) for each Q, total 2 to 10. Intercourse satisfaction score is sum of Q6, 7 and 8 of IIEF. Scores range from 0 (no attempts for Q6, did not attempt intercourse for Q7 and no intercourse for Q8) to 5 (high satisfaction) for each Q, total 0 to 15. Overall satisfaction score is sum of Q13 and 14 of IIEF. Scores range from 1 (low/no satisfaction) to 5 (high satisfaction) for each Q, total 2 to 10. Higher total scores for each domain indicate higher function. MMRM analysis was used to calculate LS mean and 95% CI. LS mean values are adjusted for baseline, treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

4. Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) Questionnaire Mean Score [Time Frame: Months 9 and 13.5]

   The EDITS questionnaire is a validated questionnaire consisting of 11 questions evaluating self-reported satisfaction with the erectile dysfunction (ED) treatment. Responses were based on the experiences during the previous 4 weeks. Each question is rated on a scale of 0 (extremely low treatment satisfaction) to 4 (extremely high treatment satisfaction). The EDITS mean score was obtained by adding each individual result for all questions, dividing by the number of questions answered. The mean scores range from 0 (extremely low treatment satisfaction) to 4 (extremely high satisfaction). The Mixed Model for Repeated Measures (MMRM) analysis was used to calculate Least Squares (LS) mean and 95% Confidence Interval (CI). LS mean values are adjusted for treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

5. Change From Baseline in Self Esteem and Relationship (SEAR) Questionnaire Score [Time Frame: Randomization (Baseline), Months 9 and 13.5]

   The SEAR questionnaire is a participant-reported measure of psychosocial outcomes in men with erectile dysfunction (ED). It consists of 14 items. Sexual Relationship domain consists of 8 items (items 1-8). Items 2-8 are rated on a scale of 1 (Never) to 5 (Always), whereas item 1 is reverse scored (1=Always and 5=Never). The total

scores for sexual relationship domain range from 8-40 with higher scores indicating better relationship. Self-Esteem subdomain contains items 9 through 12 rated on a scale of 1 (no/low self-esteem) to 5 (high self-esteem). Total scores for Self-Esteem subscale range from 4-20 with higher scores indicating higher self-esteem. The Mixed Model for Repeated Measures (MMRM) analysis was used to calculate Least Squares (LS) mean and 95% Confidence Interval (CI). LS mean values are adjusted for baseline domain score, treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

6. Global Assessment Questions (GAQ) Question 1 at Month 9 [Time Frame: Month 9]

   GAQ Question 1: Choose the one number which best describes how you perceive your ability to achieve and maintain your erections now, compared to how it was before you began taking medication in this study. Responses range from very much better (1) to very much worse (7).

7. Global Assessment Question (GAQ) Question 1 at Month 13.5 [Time Frame: Month 13.5]

   GAQ Question 1: Choose the one number which best describes how you perceive your ability to achieve and maintain your erections now, compared to how it was before you began taking medication in this study. Responses range from very much better (1) to very much worse (7).

8. Global Assessment Question (GAQ) Question 2 at Month 9 [Time Frame: Month 9]

   GAQ Question 2: Choose the one number which best describes how you perceive your sexual life is now, compared to how it was before you began taking medication in this study. Responses range from very much better (1) to very much worse (7).

9. Global Assessment Question (GAQ) Question 2 at Month 13.5 [Time Frame: Month 13.5]

   GAQ Question 2: Choose the one number which best describes how you perceive your sexual life is now, compared to how it was before you began taking medication in this study. Responses range from very much better (1) to very much worse (7).

10. Residual Erectile Function (REF) at Baseline [Time Frame: Baseline]

The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

11. Residual Erectile Function (REF) at Month 2 [Time Frame: Month 2]

    The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

12. Residual Erectile Function (REF) at Month 5 [Time Frame: Month 5]

    The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

13. Residual Erectile Function (REF) at Month 9 [Time Frame: Month 9]

    The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

14. Residual Erectile Function (REF) at Month 10.5 [Time Frame: Month 10.5]

    The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

15. Residual Erectile Function (REF) at Month 13.5 [Time Frame: Month 13.5]

    The participant is asked to rate the hardness of his erection using a 5-point grading system, with 0 (penis does not enlarge), 1 (penis is larger but not hard), 2 (penis is hard but not enough for penetration), 3 (penis is hard enough for penetration but not completely hard), 4 (penis is completely hard and fully rigid.)

16. Change From Baseline in 'Yes' Answers to Questions 1 to 5 of the Sexual Encounter Profile (SEP) [Time Frame: Randomization (Baseline), Months 9 and 10.5 and 13.5]

    Participant-assessed diary has 5 questions: Question (Q)1: erection achievement, Q2: successful penetration, Q3: successful intercourse, Q4: satisfied with erection, and Q5: satisfied with sexual experience) for each sexual encounter made over a specified period of time. SEP Q1-Q5 scores were determined as the percentage of 'Yes' responses to each of the 5 questions out of all sexual attempts recorded during the time period. The Mixed Model for Repeated Measures (MMRM) analysis was used to calculate Least Squares (LS) mean and 95% confidence interval (CI). LS mean values are adjusted for treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

17. Change From Baseline in 'Yes' Answers to Morning Erections
    [Time Frame: Randomization (Baseline), Month 10.5]

    The participants were asked to complete the morning erections diary every morning during the 4-week period before randomization and during the 6-week, Drug-Free, Washout Period. Data presented are the changes in the participant's percentage of "yes" responses relative to the number of days the question was answered during treatment. The analysis of covariance (ANCOVA) was used to calculate Least Square (LS) mean and 95% confidence interval (CI). LS mean values are adjusted for treatment, baseline morning erections frequency, age group and country.

18. Standardized Morning Erections Question (SMEQ) Score at Month 2
    [Time Frame: Month 2]

    Participants evaluated the frequency of their morning erections during the past 3-month period by answering the SMEQ ("Do you ever wake up with an erection") using a 4-point grading system ranging from 0 (Yes, regularly) to 3 (never).

19. Standardized Morning Erections Question (SMEQ) Score at Month 9
    [Time Frame: Month 9]

    Participants evaluated the frequency of their morning erections during the past 3-month period by answering the SMEQ ("Do you ever wake up with an erection") using a 4-point grading system ranging from 0 (Yes, regularly) to 3 (never).

20. Standardized Morning Erections Question (SMEQ) Score at Month 13.5
[Time Frame: Month 13.5]

    Participants evaluated the frequency of their morning erections during the past 3-month period by answering the SMEQ ("Do you ever wake up with an erection") using a 4-point grading system ranging from 0 (Yes, regularly) to 3 (never).

21. Change From Baseline in 26-item Expanded Prostate Cancer Index Composite (EPIC-26) Questionnaire Score [Time Frame: Randomization (Baseline), Months 9 and 13.5]

    EPIC-26 (participants) contains 26 items and 5 domains: Urinary Incontinence (Items 1-4), Urinary Irritative/Obstructive (Items 5-8), Bowel (Items 10-15), Sexual (Items 16-21), and Hormonal (Items 22-26). Response options for each EPIC item form a Likert scale, and multi-item scale scores are transformed linearly to a 0 to 100 scale for each domain, with higher scores representing better health-related quality of life. Responses are based on experiences during the previous 4 weeks. The Mixed Model for Repeated Measures (MMRM) analysis was used to calculate Least Squares (LS) mean and 95% confidence interval (CI). LS mean values are adjusted for baseline domain score, treatment, country, visit, visit-by-treatment, age group, and age group-by-treatment (if significant at $p<0.10$).

22. Change in Penile Length and Girth [Time Frame: Randomization (Baseline), Month 9]

    Measurements were performed with the penis in the flaccid state. The stretched penile length was measured from the tip of the glans to the pubopenile skin junction while applying tension to maximally stretch the penis. The penile circumference at midshaft was measured. All measurements were taken with a paper ruler to the nearest 0.5 centimeter (cm). The analysis of covariance (ANCOVA) was used to calculate Least Square (LS) mean and 95% confidence interval (CI). LS mean values are adjusted for treatment, baseline, age group and country.

Eligibility Criteria Go to

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 67 Years (Adult, Senior)
Sexes Eligible for Study:	Male
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- scheduled to undergo Bilateral nerve-sparing radical prostatectomy (BNSRP) for organ-confined, non-metastatic prostate cancer
- have a normal preoperative erectile function score of more or equal to 22 at screening(as evaluated by International Index of Erectile Function - Erectile Function domain (IIEF-EF))
- develop Erectile Dysfunction (ED) (defined as the consistent inability to achieve and/or maintain an erection sufficient to permit satisfactory sexual intercourse) after surgery
- have an interest in resuming sexual activity as soon as possible after surgery and anticipate having the same adult female sexual partner during the study
- agree not to use any other treatment for ED, including herbal and over-the-counter (OTC) medications, during the study
- does not require the initiation of adjuvant therapy for prostate cancer

Exclusion Criteria:

- history of ED
- have received previous or current treatment with tadalafil or any other Phosphodiesterase Type 5 (PDE5) inhibitor
- have undergone, or plan to undergo, radiation or hormonal therapy for prostate cancer
- have a history of prostatic surgery or prostatic physical treatments
- have a history of diabetes mellitus
- have a history of galactose intolerance, lapp lactase deficiency, or glucose-galactose malabsorption
- have clinically significant renal insufficiency as determined by the investigator

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01026818***

Show 52 Study Locations

Sponsors and Collaborators

Eli Lilly and Company

Investigators

Study Director: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5

More Information

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

Montorsi F, Oelke M, Henneges C, Brock G, Salonia A, d'Anzeo G, Rossi A, Mulhall JP, Büttner H. Exploratory Decision-Tree Modeling of Data from the Randomized REACTT Trial of Tadalafil Versus Placebo to Predict Recovery of Erectile Function After Bilateral Nerve-Sparing Radical Prostatectomy. Eur Urol. 2016 Sep;70(3):529-37. doi: 10.1016/j.eururo.2016.02.036. Epub 2016 Mar 3.

Patel HR, Ilo D, Shah N, Cuzin B, Chadwick D, Andrianne R, Henneges C, Barry J, Hell-Momeni K, Branicka J, Büttner H. Effects of tadalafil treatment after bilateral nerve-sparing radical prostatectomy: quality of life, psychosocial outcomes, and treatment satisfaction results from a randomized, placebo-controlled phase IV study. BMC Urol. 2015 Apr 12;15:31. doi: 10.1186/s12894-015-0022-9.

Montorsi F, Brock G, Stolzenburg JU, Mulhall J, Moncada I, Patel HR, Chevallier D, Krajka K, Henneges C, Dickson R, Büttner H. Effects of tadalafil treatment on erectile function recovery following bilateral nerve-sparing radical prostatectomy: a randomised placebo-controlled study (REACTT). Eur Urol. 2014 Mar;65(3):587-96. doi: 10.1016/j.eururo.2013.09.051. Epub 2013 Oct 13.

Responsible Party:	Eli Lilly and Company
ClinicalTrials.gov Identifier:	NCT01026818 History of Changes
Other Study ID Numbers:	13086
	H6D-EW-LVIK (Other Identifier: Eli Lilly and Company)
First Posted:	December 4, 2009 Key Record Dates
Results First Posted:	November 14, 2013
Last Update Posted:	January 14, 2014
Last Verified:	December 2013

Keywords provided by Eli Lilly and Company:
Erectile Dysfunction
Radical Prostatectomy

Additional relevant MeSH terms:

Erectile Dysfunction	Vasodilator Agents
Sexual Dysfunction, Physiological	Phosphodiesterase 5 Inhibitors
Genital Diseases, Male	Phosphodiesterase Inhibitors
Sexual Dysfunctions, Psychological	Enzyme Inhibitors
Mental Disorders	Molecular Mechanisms of Pharmacological Action
Tadalafil	Urological Agents