ClinicalTrials.gov
A service of the U.S. National Institutes of Health
Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Trial record **1 of 1** for: R096769PRE3008
Previous Study | Return to List | Next Study

Concomitant Use of PriLigy in Men Treated for Erectile Dysfunction (COUPLE)

This study has been completed.

Sponsor:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Information provided by (Responsible Party):
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

ClinicalTrials.gov Identifier:
NCT01063855

First received: February 4, 2010
Last updated: January 16, 2013
Last verified: January 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: October 4, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Erectile Dysfunction Sexual Dysfunction
Interventions:	Drug: Placebo Drug: Dapoxetine Drug: PDE5I (phosphodiesterase-5 inhibitor)

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
Study R096769-PRE-3008 was conducted at 69 study centers in 13 countries between 27 April 2010 and 31 August 2011.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 495 randomized patients, 429 patients completed the study, and 66 patients were discontinued from the study. All randomized patients (N=495) were included in the intent-to-treat analysis set of patients for efficacy and safety.

Reporting Groups

	Description
PDE5I + PLACEBO	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + DPX	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of

	erectile dysfunction.

Participant Flow: Overall Study

	PDE5I + PLACEBO	PDE5I + DPX
STARTED	**245**	**250**
COMPLETED	**208**	**221**
NOT COMPLETED	**37**	**29**
Adverse Event	**4**	**4**
Death	**0**	**1**
Lost to Follow-up	**8**	**4**
Pregnancy	**1**	**0**
Lack of Efficacy	**0**	**1**
Withdrawal by Subject	**11**	**8**
Reason not specified	**13**	**11**

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
PDE5I + PLACEBO	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + DPX	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
Total	Total of all reporting groups

Baseline Measures

	PDE5I + PLACEBO	PDE5I + DPX	Total
Overall Participants [units: participants]	**245**	**250**	**495**
Age [units: participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**228**	**231**	**459**
>=65 years	**17**	**19**	**36**
Age [units: years] Mean (Standard Deviation)	**47.9 (11.96)**	**49.5 (11.23)**	**48.7 (11.61)**
Gender [units: participants]			
Female	**0**	**0**	**0**

Male	245	250	495
Baseline BMI [units: kg/cm2] Mean (Standard Deviation)	**27.2 (4.50)**	**27.1 (4.55)**	**27.2 (4.52)**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Average Intravaginal Ejaculatory Latency Time (IELT) at Week 12 [Time Frame: Baseline, Week 12]

Measure Type	Primary
Measure Title	The Average Intravaginal Ejaculatory Latency Time (IELT) at Week 12
Measure Description	The intravaginal ejaculatory latency time (IELT) is the time it takes for a man to ejaculate during sexual intercourse (as measured by stopwatch). The data below show the average IELT measured in minutes at Baseline (before treatment) to Endpoint (after 12 weeks of treatment). In this study, patients took placebo or dapoxetine along with a stable dose of a phosphodiesterase-5 inhibitor (PDE5I) prescribed prior to study entry for the treatment of erectile dysfunction.
Time Frame	Baseline, Week 12
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo (Baseline)	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Placebo (Week 12)	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine (Baseline)	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction
PDE5I + Dapoxetine (Week 12)	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction

Measured Values

	PDE5I + Placebo (Baseline)	**PDE5I + Placebo (Week 12)**	**PDE5I + Dapoxetine (Baseline)**	**PDE5I + Dapoxetine (Week 12)**
Overall Participants [units: participants]	**241**	**230**	**249**	**240**
The Average Intravaginal Ejaculatory Latency Time (IELT) at Week 12 [units: minutes] Mean (Standard Deviation)	**1.1 (0.53)**	**3.4 (3.54)**	**1.1 (0.55)**	**5.2 (5.78)**

Statistical Analysis 1 for The Average Intravaginal Ejaculatory Latency Time (IELT) at Week 12

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Median Difference (Final Values) [4]	1.69
Standard Error of the mean	(0.430)
95% Confidence Interval	0.837 to 2.542

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observations carried forward (LPOCF) Alternative Hypothesis:- Difference at Week 12 LPOCF >0.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANCOVA model included treatment, PDE5I stratum, baseline Average IELT stratum, and region, as cofactors and baseline Average IELT as a covariate.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error was rate.
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm minus PDE5I + Placebo arm difference.

2. Secondary: The Percentage of Patients Reporting At Least a 2-category Increase in Control Over Ejaculation [Time Frame: At the end of treatment (Week 12)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Reporting At Least a 2-category Increase in Control Over Ejaculation
Measure Description	The Premature Ejaculation Profile (PEP), a patient-reported outcome measure was used to rate the patient's control over ejaculation on a 5-point scale from "Very poor, Poor, Fair, Good, to Very Good." The percentage of patients who reported at least a 2-category increase in control over ejaculation is provided in the table below.
Time Frame	At the end of treatment (Week 12)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	PDE5I + Dapoxetine
Overall Participants [units: participants]	**229**	**246**
The Percentage of Patients Reporting At Least a 2-category Increase in Control Over Ejaculation [units: Percentage of Patients]	**32.3**	**45.9**

Statistical Analysis 1 for The Percentage of Patients Reporting At Least a 2-category Increase in Control Over Ejaculation

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.001
Risk Difference (RD) [4]	13.6
95% Confidence Interval	4.9 to 22.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF). Alternative hypothesis: Difference at Week 12 LPOCF > 0.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Cochran-Mantel-Haenszel (CMH) test, controlling for type of PDE5I stratum, baseline average IELT stratum, and region.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type 1 error rate.
[4]	Other relevant estimation information:
	Risk Difference (RD) = PDE5I + Dapoxetine arm - PDE5I + placebo arm.

3. Secondary: The Percentage of Patients Who Achieved 1-category or Greater Decrease (Improvement) in Personal Distress Related to Ejaculation [Time Frame: At Endpoint (After 12 weeks of treatment)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Who Achieved 1-category or Greater Decrease (Improvement) in Personal Distress Related to Ejaculation
Measure Description	The Premature Ejaculation Profile (PEP), a patient-reported outcome measure was used to rate the patient's level of distress related to the speed of ejaculation on a 5-point scale from "Very poor, Poor, Fair, Good, to Very Good." The percentage of patients who achieved 1-category or greater decrease (improvement) in personal distress related to the speed of ejaculation is provided in the table below.
Time Frame	At Endpoint (After 12 weeks of treatment)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	PDE5I + Dapoxetine
Overall Participants [units: participants]	**229**	**246**
The Percentage of Patients Who Achieved 1-category or Greater Decrease (Improvement) in Personal Distress Related to Ejaculation [units: Percentage of Patients]	**67.2**	**76.4**

Statistical Analysis 1 for The Percentage of Patients Who Achieved 1-category or Greater Decrease (Improvement) in Personal Distress Related to Ejaculation

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.013
Risk Difference (RD) [4]	9.2
95% Confidence Interval	1.1 to 17.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF).
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	The Cochran-Mantel-Haenszel (CMH) test, controlling for type of PDE5I stratum, baseline average IELT stratum, and region.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	A hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type 1 error rate.
[4]	Other relevant estimation information:
	Risk Difference (RD) = PDE5I + Dapoxetine arm - PDE5I + Placebo arm.

4. Secondary: The Percentage of Patients Reporting a Composite Score of At Least a 2-category Increase in Control Over Ejaculation and At Least a 1-category Decrease in Personal Distress [Time Frame: At the end of treatment (Week 12)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Reporting a Composite Score of At Least a 2-category Increase in Control Over Ejaculation and At Least a 1-category Decrease in Personal Distress
Measure Description	The Premature Ejaculation Profile (PEP), a patient-reported outcome measure was used to rate the patient's level of distress related to the speed of ejaculation and control over ejaculation on a 5-point scale from "Very poor, Poor, Fair, Good, to Very Good." The percentage of patients who reported a composite score of at least a 2-category increase in control over ejaculation and at least a 1-category decrease (improvement) in personal distress is provided in the table below.
Time Frame	At the end of treatment (Week 12)

Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	PDE5I + Dapoxetine
Overall Participants [units: participants]	**229**	**246**
The Percentage of Patients Reporting a Composite Score of At Least a 2-category Increase in Control Over Ejaculation and At Least a 1-category Decrease in Personal Distress [units: Percentage of Patients]	**30.6**	**43.5**

Statistical Analysis 1 for The Percentage of Patients Reporting a Composite Score of At Least a 2-category Increase in Control Over Ejaculation and At Least a 1-category Decrease in Personal Distress

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.002
Odds Ratio (OR) [4]	1.78
95% Confidence Interval	1.204 to 2.619

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF) Alternative Hypothesis: PDE5I + Dapoxetine is superior to PDE5I + Placebo with respect to the outcome measure at Week 12 LPOCF.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic Regression model included treatment, type of PDE5i stratum, baseline Average IELT stratum, and region, as factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error.
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm over PDE5I + Placebo arm ratio.

5. Secondary: The Percentage of Patients Who Achieved a 1-category or Greater Increase in Satisfaction With Sexual Intercourse [Time Frame: Endpoint (After 12 weeks of treatment)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Who Achieved a 1-category or Greater Increase in Satisfaction With Sexual Intercourse
Measure Description	The Premature Ejaculation Profile (PEP), a patient-reported outcome measure was used to rate the patient's level of satisfaction with intercourse on a 5-point scale from "Very poor, Poor, Fair, Good, to Very Good." The percentage of patients who achieved 1-category or greater increase in satisfaction with sexual intercourse is provided in the table below.
Time Frame	Endpoint (After 12 weeks of treatment)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	**PDE5I + Dapoxetine**
Overall Participants [units: participants]	**229**	**246**
The Percentage of Patients Who Achieved a 1-category or Greater Increase in Satisfaction With Sexual Intercourse [units: Percentage of Patients]	**55.0**	**66.3**

Statistical Analysis 1 for The Percentage of Patients Who Achieved a 1-category or Greater Increase in Satisfaction With Sexual Intercourse

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.007
Odds Ratio (OR) [4]	1.63
95% Confidence Interval	1.108 to 2.394

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carrried forward (LPOCF) Alternative Hypothesis:- PDE5I + Dapoxetine is superior to PDE5I + Placebo with respect to the outcome measure at Week 12 LPOCF.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic Regression model included treatment, type of PDE5i stratum, baseline Average IELT stratum, and region, as factors.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error was rate.
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm over PDE5I + Placebo arm ratio.

6. Secondary: The Percentage of Patients Reporting At Least a "Better" Response to Treatment [Time Frame: Endpoint (After 12 weeks of treatment)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Reporting At Least a "Better" Response to Treatment
Measure Description	The "Clinical Global Impression of Change" (CGIC) was used to assess the degree of improvement the patient experienced with premature ejaculation (PE) since initiating treatment with study drug on a 7-point scale from "Much worse, Worse, Slightly worse, No change, Slightly better, Better, to Much better". The percentage of patients who reported improvement in PE of at least "better" at Endpoint (after 12 weeks of treatment) is provided in the table below.
Time Frame	Endpoint (After 12 weeks of treatment)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	PDE5I + Dapoxetine
Overall Participants [units: participants]	**229**	**246**
The Percentage of Patients Reporting At Least a "Better" Response to Treatment [units: Percentage of Patients]	**35.4**	**56.5**

Statistical Analysis 1 for The Percentage of Patients Reporting At Least a "Better" Response to Treatment

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.001

Odds Ratio (OR) [4]	2.42
95% Confidence Interval	1.642 to 3.568

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF) Alternative Hypothesis:- PDE5I + Dapoxetine is superior to PDE5I + Placebo with respect to the outcome measure at Week 12.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic Regression model included treatment, type of PDE5i stratum, baseline Average IELT stratum, and region, as factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error was rate
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm over PDE5I + Placebo arm ratio.

7. Secondary: The Percentage of Patients Who Reported At Least a 1-category Decrease (Improvement) in Interpersonal Difficulty Related to Ejaculation [Time Frame: Endpoint (After 12 weeks of treatment)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Who Reported At Least a 1-category Decrease (Improvement) in Interpersonal Difficulty Related to Ejaculation
Measure Description	The Premature Ejaculation Profile (PEP), a patient-reported outcome measure was used to rate the patient's level of interpersonal difficulty related to ejaculation on a 5-point scale from "Very poor, Poor, Fair, Good, to Very Good." The percentage of patients who reported at least a 1-category decrease (improvement) in interpersonal difficulty related to ejaculation is provided in the table below.
Time Frame	Endpoint (After 12 weeks of treatment)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	**PDE5I + Dapoxetine**
Overall Participants [units: participants]	**229**	**246**

The Percentage of Patients Who Reported At Least a 1-category Decrease (Improvement) in Interpersonal Difficulty Related to Ejaculation [units: Percentage of Patients]	**61.6**	**67.5**

Statistical Analysis 1 for The Percentage of Patients Who Reported At Least a 1-category Decrease (Improvement) in Interpersonal Difficulty Related to Ejaculation

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	>0.05
Odds Ratio (OR) [4]	1.33
95% Confidence Interval	0.897 to 1.965

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF) Alternative Hypothesis:- PDE5I + Dapoxetine is superior to PDE5I + Placebo with respect to the outcome measure at Week 12 LPOCF.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic Regression model included treatment, type of PDE5i stratum, baseline Average IELT stratum, and region, as factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error was rate.
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm over PDE5I + Placebo arm ratio.

8. Secondary: The Percentage of Patients Reporting At Least a "Slightly Better" Response to Treatment [Time Frame: Endpoint (After 12 weeks of treatment)]

Measure Type	Secondary
Measure Title	The Percentage of Patients Reporting At Least a "Slightly Better" Response to Treatment
Measure Description	The "Clinical Global Impression of Change" (CGIC) was used to assess the degree of improvement the patient experienced with premature ejaculation (PE) since initiating treatment with study drug on a 7-point scale from "Much worse, Worse, Slightly worse, No change, Slightly better, Better, to Much better". The percentage of patients who reported improvement in PE of at least "slightly better" at Endpoint (after 12 weeks of treatment) is provided in the table below.
Time Frame	Endpoint (After 12 weeks of treatment)
Safety Issue	No

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.
The intent-to-treat (ITT) analysis set included all randomized patients. Missing efficacy data at Week 12 was imputed based on the last postbaseline observation carried forward (LPOCF) method.

Reporting Groups

	Description
PDE5I + Placebo	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to

	be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + Dapoxetine	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Measured Values

	PDE5I + Placebo	PDE5I + Dapoxetine
Overall Participants [units: participants]	**230**	**240**
The Percentage of Patients Reporting At Least a "Slightly Better" Response to Treatment [units: Percentage of Patients]	**66.9**	**91.3**

Statistical Analysis 1 for The Percentage of Patients Reporting At Least a "Slightly Better" Response to Treatment

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.21
95% Confidence Interval	1.425 to 3.423

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null Hypothesis: No difference at Week 12 last postbaseline observation carried forward (LPOCF) Alternative Hypothesis:- PDE5I + Dapoxetine is superior to PDE5I + Placebo with respect to the outcome measure at Week 12.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic Regression model included treatment, type of PDE5i stratum, baseline Average IELT stratum, and region, as factors.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	To properly adjust for multiplicity, a hierarchical (step-down) testing procedure with a priori ordered hypothesis was used to control the family-wise type I error was rate.
[4]	Other relevant estimation information:
	Estimates are based on two-stage sequential analysis using information fraction based weighted test statistics for PDE5I + Dapoxetine arm over PDE5I + Placebo arm ratio.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were reported for the duration of the study; each patient participated in the study for approximately 18 weeks.
Additional Description	No text entered.

Reporting Groups

	Description
PDE5I + PLACEBO	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.
PDE5I + DPX	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once

	every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Serious Adverse Events

	PDE5I + PLACEBO	PDE5I + DPX
Total, serious adverse events		
# participants affected / at risk	**4/245 (1.63%)**	**3/250 (1.20%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Cardiac disorders		
Myocardial Infarction * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Musculoskeletal and connective tissue disorders		
Juvenile Arthritis * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Meningioma * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Renal Cell Carcinoma * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Nervous system disorders		
Syncope * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Renal and urinary disorders		
Renal Colic * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Social circumstances		
Miscarriage of Partner * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 14.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were reported for the duration of the study; each patient participated in the study for approximately 18 weeks.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0

Reporting Groups

	Description
PDE5I + PLACEBO	Placebo tablets identical in appearance to dapoxetine taken 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study

	entry for the treatment of erectile dysfunction.
PDE5I + DPX	Dapoxetine 30 mg to 60 mg tablets 1 to 3 hours before sexual activity prn (as needed) not to be taken more than once every 24 hours for 12 weeks + PDE5I (phosphodiesterase-5 inhibitor) prescribed prior to study entry for the treatment of erectile dysfunction.

Other Adverse Events

	PDE5I + PLACEBO	PDE5I + DPX
Total, other (not including serious) adverse events		
# participants affected / at risk	**45/245 (18.37%)**	**73/250 (29.20%)**
Cardiac disorders		
Palpitations [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Congenital, familial and genetic disorders		
Phimosis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Ear and labyrinth disorders		
Tinnitus [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**1/250 (0.40%)**
Vertigo [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**4/250 (1.60%)**
Vertigo Positional [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Eye disorders		
Eye Pain [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Eyelid Ptosis [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Vision Blurred [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Gastrointestinal disorders		
Abdominal Pain [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Abdominal Pain Upper [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Diarrhoea [*1]		
# participants affected / at risk	**2/245 (0.82%)**	**9/250 (3.60%)**
Dry Mouth [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Dyspepsia [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**3/250 (1.20%)**
Flatulence [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Gastritis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**1/250 (0.40%)**
Gastrooesophageal Reflux Disease [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Inguinal Hernia [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**

Nausea [*1]		
# participants affected / at risk	**3/245 (1.22%)**	**23/250 (9.20%)**
Toothache [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**2/250 (0.80%)**
Vomiting [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**1/250 (0.40%)**
General disorders		
Adverse Drug Reaction [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Asthenia [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Chills [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Fatigue [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**2/250 (0.80%)**
Irritability [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Hepatobiliary disorders		
Cholelithiasis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Infections and infestations		
Bacterial Food Poisoning [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Ear Infection Viral [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Gastroenteritis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**1/250 (0.40%)**
Influenza [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**2/250 (0.80%)**
Lower Respiratory Tract Infection [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**4/245 (1.63%)**	**3/250 (1.20%)**
Oral Herpes [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Pharyngitis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**2/250 (0.80%)**
Respiratory Tract Infection Viral [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Upper Respiratory Tract Infection [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**4/250 (1.60%)**
Injury, poisoning and procedural complications		
Arthropod Bite [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Back Injury [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Contusion [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**

Hand Fracture [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Joint Injury [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Joint Sprain [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Meniscus Lesion [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Procedural Pain [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Road Traffic Accident [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Tendon Rupture [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Thermal Burn [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Tooth Fracture [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Investigations		
Blood Pressure Increased [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Gastric Ph Decreased [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Metabolism and nutrition disorders		
Decreased Appetite [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Hypertriglyceridaemia [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Musculoskeletal and connective tissue disorders		
Arthralgia [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**1/250 (0.40%)**
Back Pain [*1]		
# participants affected / at risk	**2/245 (0.82%)**	**1/250 (0.40%)**
Musculoskeletal Chest Pain [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Musculoskeletal Pain [*1]		
# participants affected / at risk	**2/245 (0.82%)**	**0/250 (0.00%)**
Musculoskeletal Stiffness [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Myalgia [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Neck Pain [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Nervous system disorders		
Disturbance in Attention [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Dizziness [*1]		
# participants affected / at risk	**2/245 (0.82%)**	**6/250 (2.40%)**

Dizziness Exertional [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Dizziness Postural [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**6/250 (2.40%)**
Headache [*1]		
# participants affected / at risk	**12/245 (4.90%)**	**11/250 (4.40%)**
Lethargy [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Sedation [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Somnolence [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Syncope [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Psychiatric disorders		
Agitation [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Anxiety [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Euphoric Mood [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Insomnia [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**3/250 (1.20%)**
Renal and urinary disorders		
Haematuria [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Micturition Urgency [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Nephrolithiasis [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Nocturia [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Pollakiuria [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Renal Cyst [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Reproductive system and breast disorders		
Benign Prostatic Hyperplasia [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Erectile Dysfunction [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Penis Disorder [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Prostatomegaly [*1]		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Haemoptysis [*1]		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**

Hiccups * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Nasal Congestion * 1		
# participants affected / at risk	**3/245 (1.22%)**	**0/250 (0.00%)**
Oropharyngeal Pain * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Skin and subcutaneous tissue disorders		
Erythema * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Hyperhidrosis * 1		
# participants affected / at risk	**0/245 (0.00%)**	**3/250 (1.20%)**
Photosensitivity Reaction * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Pruritus * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Pruritus Generalised * 1		
# participants affected / at risk	**1/245 (0.41%)**	**0/250 (0.00%)**
Skin Lesion * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**
Vascular disorders		
Flushing * 1		
# participants affected / at risk	**3/245 (1.22%)**	**0/250 (0.00%)**
Hypertension * 1		
# participants affected / at risk	**0/245 (0.00%)**	**1/250 (0.40%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 14.0

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: CDTL, Cardiovascular and Metabolism
Organization: Janssen Research & Development, LLC
phone: 1 908 704-4648

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

McMahon CG, Giuliano F, Dean J, Hellstrom WJ, Bull S, Tesfaye F, Sharma O, Rivas DA, Aquilina JW. Efficacy and safety of dapoxetine in men with premature ejaculation and concomitant erectile dysfunction treated with a phosphodiesterase type 5 inhibitor: randomized, placebo-controlled, phase III study. J Sex Med. 2013 Sep;10(9):2312-25. doi: 10.1111/jsm.12236.

Responsible Party:	Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
ClinicalTrials.gov Identifier:	NCT01063855 History of Changes
Other Study ID Numbers:	CR016486 **R096769PRE3008** (Other Identifier: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.) 2009-013616-12 (EudraCT Number)
Study First Received:	February 4, 2010
Results First Received:	October 4, 2012
Last Updated:	January 16, 2013
Health Authority:	United States: Food and Drug Administration Great Britain: Medicines and Healthcare Products Regulatory Agency United States: Federal Government

Disclaimer

Information in this posting shall not be considered to be a claim for any marketed Product. Some information in this posting may differ from the approved labeling for the Product. Please refer to the full prescribing information for indications and proper use of the product.