ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/03/2014

ClinicalTrials.gov ID: NCT01325350

Study Identification

Unique Protocol ID:	192024-058
Brief Title:	Safety and Efficacy Study of Bimatoprost in the Treatment of Women With Female Pattern Hair Loss
Official Title:	
Secondary IDs:	2011-000380-27 [EudraCT Number]

Study Status

Record Verification:	March 2014
Overall Status:	Completed
Study Start:	June 2011
Primary Completion:	July 2012 [Actual]
Study Completion:	September 2012 [Actual]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No

IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 107908 Serial Number: Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration

Study Description

Brief Summary:	This study will evaluate the safety and efficacy of 3 doses of bimatoprost solution compared with vehicle and over-the-counter (OTC) minoxidil 2% solution in women with female pattern hair loss. All treatments will be provided in a double-blinded fashion except for minoxidil 2% solution which will be provided open-label.
Detailed Description:	

Conditions

Conditions:	Alopecia Baldness
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	5
Masking:	Double Blind (Subject, Investigator, Outcomes Assessor)

Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	306 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: bimatoprost Formulation A Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.	Drug: bimatoprost Formulation A Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.
Experimental: bimatoprost Formulation B Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.	Drug: bimatoprost Formulation B Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.
Experimental: bimatoprost Formulation C Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.	Drug: bimatoprost Formulation C Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.
Placebo Comparator: bimatoprost vehicle solution Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.	Drug: bimatoprost vehicle solution Approximately one mL dose applied evenly onto pre-specified area on scalp, once daily for 6 months.
Active Comparator: minoxidil 2% solution Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.	Drug: minoxidil 2% solution Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months. Other Names: • Rogaine® • Regaine®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	59 Years
Gender:	Female
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Mild to moderate female pattern hair loss with ongoing hair loss for at least 1 year
- Willingness to have micro-dot-tattoo applied to scalp
- Willingness to maintain same hair style, length and hair color during study

Exclusion Criteria:

- Drug or alcohol abuse within 12 months
- HIV positive
- Received hair transplants or had scalp reductions
- Use of hair weaves, hair extensions or wigs within 3 months
- Oral or topical minoxidil treatment within 6 months
- Application of topical steroids or nonsteroidal anti-inflammatory drugs (NSAIDs) to scalp within 4 weeks

Contacts/Locations

Study Officials: Medical Director
Study Director
Allergan, Inc.

Locations: United States, Oregon
Portland, Oregon, United States

Germany
Berlin, Germany

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one milliliter (mL) of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL of minoxidil 2% solution applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Overall Study

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Started	61	61	61	61	62
Completed	55	56	44	52	50
Not Completed	6	5	17	9	12
Adverse Event	3	3	3	1	2
Pregnancy	0	0	1	0	1
Lost to Follow-up	1	0	5	1	5
Personal Reasons	2	1	6	5	3
Protocol Violation	0	0	0	1	0
Withdrawal by Subject	0	0	1	1	0
Did Not Receive Treatment	0	1	1	0	1

Baseline Characteristics

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Baseline Measures

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution	Total
Number of Participants	61	61	61	61	62	306
Age, Customized [units: Participants]						
18 to 34 years	12	13	12	13	12	62
35 to 59 years	49	48	49	48	50	244
Gender, Male/Female [units: Participants]						
Female	61	61	61	61	62	306
Male	0	0	0	0	0	0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Target Area Hair Count (TAHC)
Measure Description	TAHC was measured using digital imaging analysis and was reported in terminal hairs/centimeters squared (cm^2). A positive change from Baseline indicated improvement (increase in the number of terminal hairs). A negative change from Baseline indicated worsening (decrease in the number of terminal hairs).

Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	61	60	60	61	61
Change From Baseline in Target Area Hair Count (TAHC) [units: terminal hairs/cm^2] Mean (Standard Deviation)					
Baseline	153.1 (54.78)	161.1 (63.85)	145.2 (63.42)	163.0 (57.28)	156.3 (55.46)
Change from Baseline at Month 6	-0.4 (17.10)	-3.5 (18.21)	4.3 (16.82)	1.1 (20.44)	13.6 (18.72)

2. Primary Outcome Measure:

Measure Title	Percentage of Participants in Each Response Category of the Subject Self Assessment in Alopecia (SSA) Score

Measure Description	The SSA score measured scalp hair growth. Using a 7-point scale, participants answered the Question: "Since the start of the study, the amount of my hair has?": Greatly Increased, Moderately Increased, Slightly Increased, Remained the Same, Slightly Decreased, Moderately Decreased or Greatly Decreased. The percentage of participants in each response category is presented.
Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	58	60	54	61	56
Percentage of Participants in Each Response Category of the Subject Self Assessment in Alopecia (SSA) Score [units: Percentage of participants]					
Greatly Increased	3.4	3.3	9.3	3.3	7.1
Moderately Increased	17.2	20.0	16.7	18.0	28.6
Slightly Increased	34.5	21.7	16.7	24.6	35.7
Remained the Same	20.7	33.3	38.9	29.5	19.6

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Slightly Decreased	19.0	11.7	13.0	13.1	5.4
Moderately Decreased	1.7	8.3	5.6	8.2	1.8
Greatly Decreased	3.4	1.7	0.0	3.3	1.8

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants in Each Response Category of the Investigator Global Assessment (IGA) Score
Measure Description	The investigator compared the participant's scalp hair growth at Month 6 to a photograph of the scalp taken at Baseline and using the 7-point IGA score, the investigator answered the question: "Since the start of the study, the amount of the subject's hair has?": Greatly Increased, Moderately Increased, Slightly Increased, Remained the Same, Slightly Decreased, Moderately Decreased or Greatly Decreased. The percentage of participants in each response category is presented.
Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	58	60	54	61	56
Percentage of Participants in Each Response Category of the Investigator Global Assessment (IGA) Score [units: Percentage of participants]					
Greatly Increased	5.2	3.3	7.4	1.6	1.8
Moderately Increased	12.1	10.0	11.1	14.8	16.1
Slightly Increased	24.1	35.0	25.9	23.0	37.5
Remained the Same	39.7	40.0	51.9	54.1	41.1
Slightly Decreased	15.5	10.0	3.7	6.6	3.6
Moderately Decreased	3.4	1.7	0.0	0.0	0.0
Greatly Decreased	0.0	0.0	0.0	0.0	0.0

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants in Each Response Category of the Global Panel Review (GPR) Score
Measure Description	At the completion of the study, 3 independent dermatologists using the 7-point GPR score compared photographs of the participant's scalp hair growth at Month 6 to Baseline and answered the question: "Compared with the baseline image, the amount of the subject's hair has?": Greatly Increased, Moderately Increased, Slightly Increased, Remained the Same, Slightly Decreased, Moderately Decreased or Greatly Decreased. The percentage of participants in each response category is presented.
Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	55	59	48	61	53
Percentage of Participants in Each Response Category of the Global Panel Review (GPR) Score [units: Percentage of participants]					
Greatly Increased	0.0	0.0	0.0	0.0	0.0
Moderately Increased	1.8	0.0	2.1	1.6	0.0
Slightly Increased	0.0	6.8	6.3	6.6	17.0
Remained the Same	87.3	81.4	81.3	88.5	79.2
Slightly Decreased	10.9	11.9	10.4	3.3	1.9
Moderately Decreased	0.0	0.0	0.0	0.0	1.9
Greatly Decreased	0.0	0.0	0.0	0.0	0.0

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Target Area Hair Width (TAHW)

Measure Description	Digital imaging analysis was used to measure TAHW in millimeters/centimeters squared (mm/cm^2). The diameters of all terminal hairs (individual hairs ≥ 30 microns) in the target area were summed and reported together. A positive change from Baseline indicated improvement (increase in the diameter of terminal hairs). A negative change from Baseline indicated worsening (decrease in the diameter of terminal hairs).
Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	61	60	60	61	61
Change From Baseline in Target Area Hair Width (TAHW) [units: mm/cm^2] Mean (Standard Deviation)					
Baseline	8.92 (3.444)	9.64 (3.308)	8.86 (3.977)	10.13 (4.165)	9.76 (3.698)
Change from Baseline from Month 6	0.13 (1.198)	-0.19 (1.067)	0.30 (1.263)	0.07 (1.183)	0.87 (1.315)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in Target Area Hair Darkness (TAHD)
Measure Description	Digital imaging analysis was used to measure TAHD. The darkness of all terminal hairs (individual hairs ≥ 30 microns) in the target area were summed and divided by total number of terminal hairs in the same target area and was reported as intensity units. A positive change from Baseline indicated improvement (increase in the darkness of terminal hairs).
Time Frame	Baseline, Month 6
Safety Issue?	No

Analysis Population Description

Participants from the Modified Intent-to-Treat Population (all randomized participants who received treatment and had both Baseline and post-Baseline measurements) who had data available for this outcome measure.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Measured Values

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
Number of Participants Analyzed	61	60	60	61	61
Change From Baseline in Target Area Hair Darkness (TAHD) [units: Intensity units] Mean (Standard Deviation)					
Baseline	95.63 (23.837)	100.12 (25.077)	92.76 (19.433)	96.90 (22.678)	93.07 (20.667)
Change from Baseline at Month 6	2.94 (13.084)	4.22 (13.159)	2.11 (14.674)	2.07 (11.486)	2.12 (11.561)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	The Safety Population (all participants who received at least 1 dose of study treatment) was used to calculate the number of participants at risk for treatment-emergent Serious Adverse Events and treatment-emergent Adverse Events.

Reporting Groups

	Description
Bimatoprost Formulation A	Approximately one mL of bimatoprost Formulation A applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation B	Approximately one mL of bimatoprost Formulation B applied evenly onto pre-specified area on scalp, once daily for 6 months.
Bimatoprost Formulation C	Approximately one mL of bimatoprost Formulation C applied evenly onto pre-specified area on scalp, once daily for 6 months.
Vehicle to Bimatoprost	Approximately one mL of vehicle to bimatoprost applied evenly onto pre-specified area on scalp, once daily for 6 months.
Minoxidil 2% Solution	Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.

Serious Adverse Events

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/61 (6.56%)	4/60 (6.67%)	3/60 (5%)	1/61 (1.64%)	1/61 (1.64%)
General disorders					
Death [A] [1] †	0/61 (0%)	0/60 (0%)	1/60 (1.67%)	0/61 (0%)	0/61 (0%)
Hepatobiliary disorders					
Cholecystitis [A] [1] †	0/61 (0%)	1/60 (1.67%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Infections and infestations					
Appendicitis [A] [1] †	0/61 (0%)	1/60 (1.67%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Gastroenteritis [A] [1] †	0/61 (0%)	0/60 (0%)	1/60 (1.67%)	0/61 (0%)	0/61 (0%)

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders					
Arthralgia A [1] *	0/61 (0%)	1/60 (1.67%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Chondropathy A [1] †	0/61 (0%)	0/60 (0%)	0/60 (0%)	0/61 (0%)	1/61 (1.64%)
Intervertebral disc protrusion A [2] †	0/61 (0%)	0/60 (0%)	1/60 (1.67%)	1/61 (1.64%)	0/61 (0%)
Osteoarthritis A [2] †	2/61 (3.28%)	0/60 (0%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Rotator cuff syndrome A [1] †	0/61 (0%)	1/60 (1.67%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Benign ovarian tumour A [1] †	0/61 (0%)	1/60 (1.67%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Nervous system disorders					
Syncope A [1] *	1/61 (1.64%)	0/60 (0%)	0/60 (0%)	0/61 (0%)	0/61 (0%)
Respiratory, thoracic and mediastinal disorders					
Pneumothorax A [1] †	1/61 (1.64%)	0/60 (0%)	0/60 (0%)	0/61 (0%)	0/61 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (15.0)

[1] Event not treatment-related
[2] Events not treatment-related

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	17/61 (27.87%)	17/60 (28.33%)	15/60 (25%)	20/61 (32.79%)	24/61 (39.34%)
General disorders					
Application site dryness A *	1/61 (1.64%)	1/60 (1.67%)	0/60 (0%)	2/61 (3.28%)	4/61 (6.56%)

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 2% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Application site pruritis [A] *	0/61 (0%)	3/60 (5%)	2/60 (3.33%)	0/61 (0%)	5/61 (8.2%)
Infections and infestations					
Nasopharyngitis [A] †	1/61 (1.64%)	2/60 (3.33%)	2/60 (3.33%)	6/61 (9.84%)	7/61 (11.48%)
Sinusitis [A] †	1/61 (1.64%)	3/60 (5%)	1/60 (1.67%)	2/61 (3.28%)	1/61 (1.64%)
Upper respiratory tract infection [A] †	6/61 (9.84%)	5/60 (8.33%)	0/60 (0%)	1/61 (1.64%)	2/61 (3.28%)
Injury, poisoning and procedural complications					
Procedural pain [A] *	2/61 (3.28%)	1/60 (1.67%)	3/60 (5%)	2/61 (3.28%)	1/61 (1.64%)
Nervous system disorders					
Headache [A] *	1/61 (1.64%)	1/60 (1.67%)	4/60 (6.67%)	5/61 (8.2%)	1/61 (1.64%)
Skin and subcutaneous tissue disorders					
Hypertrichosis [A] *	5/61 (8.2%)	1/60 (1.67%)	0/60 (0%)	1/61 (1.64%)	3/61 (4.92%)
Vascular disorders					
Hypertension [A] †	0/61 (0%)	0/60 (0%)	3/60 (5%)	1/61 (1.64%)	0/61 (0%)

† Indicates events were collected by systematic assessment.
* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (15.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

A 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 90 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head,
Organization: Allergan, Inc
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