

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 04/08/2014

ClinicalTrials.gov ID: NCT01325337

Study Identification

Unique Protocol ID: 192024-057

Brief Title: Safety and Efficacy Study of Bimatoprost in the Treatment of Men With Androgenic Alopecia

Official Title:

Secondary IDs: 2011-000379-15 [EudraCT Number]

Study Status

Record Verification: April 2014

Overall Status: Completed

Study Start: June 2011

Primary Completion: August 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 5% solution in men with androgenic alopecia. All treatments will be provided in a double-blinded fashion except for minoxidil 5% solution which will be provided open-label.

Detailed Description:

Conditions

Conditions: Alopecia
Alopecia, Androgenetic
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: 307 [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 5% solution Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months.	Drug: minoxidil 5% solution Approximately one mL dose applied evenly onto pre-specified area on scalp, twice daily for 6 months. Other Names: <ul style="list-style-type: none">• Rogaine®• Regaine®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 49 Years

Gender: Male

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Mild to moderate male pattern baldness (androgenic alopecia) 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:

Study Results

▶ 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 5% Solution	Approximately one mL of minoxidil 5% 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 5% Solution
Started	61	61	62	62	61
Completed	56	52	53	52	53
Not Completed	5	9	9	10	8
Adverse Event	0	2	2	1	2
Lost to Follow-up	2	2	2	1	2
Personal Reasons	2	5	4	8	3
Withdrawal by Subject	1	0	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.

	Description
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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution	Total
Number of Participants	61	61	62	62	61	307
Age, Customized [units: Participants]						
18 to 34 years	19	18	20	18	18	93
35 to 50 years	42	43	42	44	43	214
Gender, Male/Female [units: Participants]						
Female	0	0	0	0	0	0
Male	61	61	62	62	61	307

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).
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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	60	61	61	61	61
Change From Baseline in Target Area Hair Count (TAHC) [units: terminal hairs/cm ²] Mean (Standard Deviation)					
Baseline	135.0 (58.80)	145.7 (57.25)	151.5 (60.40)	143.7 (55.42)	132.7 (53.14)
Change from Baseline at Month 6	13.1 (21.69)	6.1 (19.80)	6.3 (22.05)	4.1 (15.59)	21.9 (19.30)

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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	58	59	60	58	58
Percentage of Participants in Each Response Category of the Subject Self Assessment in Alopecia (SSA) Score [units: Percentage of participants]					
Greatly Increased	0.0	1.7	0.0	1.7	5.2
Moderately Increased	8.6	11.9	11.7	6.9	27.6
Slightly Increased	31.0	23.7	16.7	19.0	34.5
Remained the Same	43.1	40.7	41.7	51.7	22.4
Slightly Decreased	13.8	15.3	20.0	19.0	8.6
Moderately Decreased	3.4	5.1	6.7	1.7	1.7
Greatly Decreased	0.0	1.7	3.3	0.0	0.0

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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	58	59	61	58	58
Percentage of Participants in Each Response Category of the Investigator Global Assessment (IGA) Score [units: Percentage of participants]					
Greatly Increased	0.0	5.1	0.0	0.0	8.6
Moderately Increased	12.1	6.8	4.9	6.9	24.1

	Bimatoprost Formulation A	Bimatoprost Formulation B	Bimatoprost Formulation C	Vehicle to Bimatoprost	Minoxidil 5% Solution
Slightly Increased	29.3	28.8	23.0	25.9	15.5
Remained the Same	48.3	55.9	63.9	63.8	44.8
Slightly Decreased	10.3	3.4	8.2	3.4	6.9
Moderately Decreased	0.0	0.0	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.

	Description
Minoxidil 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	57	56	58	56	58
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	3.5	1.8	0.0	0.0	5.2
Slightly Increased	17.5	10.7	8.6	8.9	39.7
Remained the Same	71.9	73.2	74.1	75.0	50.0
Slightly Decreased	7.0	14.3	17.2	16.1	3.4
Moderately Decreased	0.0	0.0	0.0	0.0	1.7
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 width) in the target area were summed and reported together. A positive change from Baseline indicated improvement (increase 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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	60	61	61	61	61
Change From Baseline in Target Area Hair Width (TAHW) [units: mm/cm ²] Mean (Standard Deviation)					
Baseline	7.83 (3.879)	8.34 (3.716)	8.59 (3.668)	8.35 (3.494)	7.82 (3.436)
Change from Baseline at Month 6	0.76 (1.390)	0.25 (1.185)	0.12 (1.228)	0.13 (0.839)	1.29 (1.117)

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 \geq 30 microns in width) 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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
Number of Participants Analyzed	60	61	61	61	61
Change From Baseline in Target Area Hair Darkness (TAHD) [units: Intensity units] Mean (Standard Deviation)					
Baseline	106.88 (19.282)	103.85 (21.950)	100.81 (18.041)	104.03 (17.863)	99.57 (28.139)
Change from Baseline at Month 6	1.19 (12.000)	2.92 (14.686)	4.04 (11.061)	0.65 (10.626)	3.40 (12.888)

Reported Adverse Events

Time Frame	[Not specified]
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Additional Description	The Safety Population, that consisted of 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.
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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 5% Solution	Approximately one mL of minoxidil 5% solution 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 5% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/61 (0%)	1/61 (1.64%)	1/62 (1.61%)	1/62 (1.61%)	0/61 (0%)
Injury, poisoning and procedural complications					
Femur fracture ^{A [1] †}	0/61 (0%)	0/61 (0%)	1/62 (1.61%)	0/62 (0%)	0/61 (0%)
Humerus fracture ^{A [1] †}	0/61 (0%)	0/61 (0%)	1/62 (1.61%)	0/62 (0%)	0/61 (0%)
Radius fracture ^{A [1] †}	0/61 (0%)	0/61 (0%)	1/62 (1.61%)	0/62 (0%)	0/61 (0%)
Tibia fracture ^{A [1] †}	0/61 (0%)	0/61 (0%)	1/62 (1.61%)	0/62 (0%)	0/61 (0%)
Wrist fracture ^{A [1] †}	0/61 (0%)	0/61 (0%)	1/62 (1.61%)	0/62 (0%)	0/61 (0%)
Musculoskeletal and connective tissue disorders					
Back pain ^{A [1] *}	0/61 (0%)	1/61 (1.64%)	0/62 (0%)	0/62 (0%)	0/61 (0%)
Osteonecrosis ^{A [1] †}	0/61 (0%)	0/61 (0%)	0/62 (0%)	1/62 (1.61%)	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

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 5% Solution
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/61 (9.84%)	11/61 (18.03%)	4/62 (6.45%)	7/62 (11.29%)	10/61 (16.39%)
General disorders					
Application site pruritis ^{A *}	1/61 (1.64%)	4/61 (6.56%)	0/62 (0%)	0/62 (0%)	7/61 (11.48%)
Infections and infestations					
Nasopharyngitis ^{A †}	5/61 (8.2%)	7/61 (11.48%)	4/62 (6.45%)	7/62 (11.29%)	3/61 (4.92%)

† 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
 Phone: 714-246-4500

