Clinical Safety and Efficacy of an At-Home, Dual Wavelength Red Light Hair Growth System in Subjects with Androgenetic Alopecia

Rodney Sinclair[1], Dedee Murrell[2], Lynda Spelman[3], Johanna Kuchel[4]
Nicholas Medendorp[5], Matt Womble[5], Nathan Stasko[5]

[1] Department of Dermatology, University of Melbourne, East Melbourne, Australia [2] Department of Dermatology, University of New South Wales, Kensington, Australia [3] Queensland Institute of Dermatology, Queensland, Australia [4] Department of Dermatology, Royal Prince Alfred Hospital, Camperdown, Australia [5] PhotonMD Inc., Durham, North Carolina (nstasko@photonmd.com)

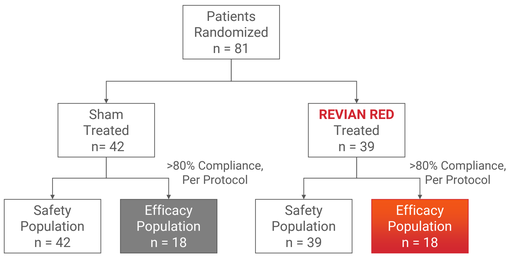
Objective

REVIAN Red® is an FDA-cleared low-level light therapy device (K173729) used to promote hair growth. To evaluate the safety and efficacy of the dual wavelength LED light device in men and women with androgenetic alopecia we conducted a 26 week, multicenter, prospective, randomized, controlled, double-blind, study.

Dual Wavelength Device
(REVIAN® RED)

Methods

Eighty-one subjects were randomized to either a dual wavelength 620 nm and 660 nm light therapy device paired with a Bluetooth-connected mobile app (REVIAN RED System) or to a sham comparator device with a similar user experience through the mobile app to track daily treatment compliance between both groups. Device usage was fixed at once daily, 10-minute treatment durations for a period of 26-weeks. The trial population consisted of adult men and women between 18 and 65 years of age with a diagnosis of androgenetic alopecia, consistent with males who have Norwood Hamilton Classification IIa to V patterns of hair loss and females who have Ludwig-Savin Scale I-1 to I-4, II -1, II-2 or frontal, both with Fitzpatrick Skin Types I - IV.



Demographics

	Dual Wavelength Device (n = 39)	Sham Device (n = 42)
Gender		
Male	30 (77%)	30 (71%)
Female	9 (23%)	12 (29%)
Age		
Mean	41	44
Min to Max	19 - 64	20 - 69
Fitzpatrick Skin Type		
Type I	1 (3%)	1 (2%)
Type II	13 (33%)	15 (36%)
Type III	14 (36%)	14 (33%)
Type IV	11 (28%)	12 (29%)
Disposition		
Completed	35 (90%)	37 (88%)
Discontinued	4 (10%)	5 (12%)

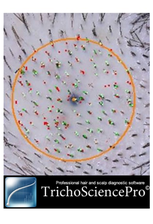
Treatment Emergent Adverse Events

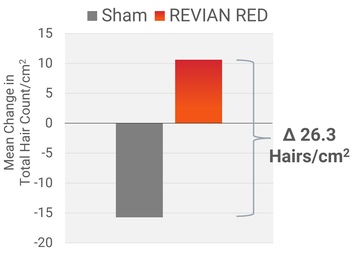
	Dual Wavelength Device (n = 39)	Sham Device (n = 42)
Overall Summary of TEAE		
Subjects with at least one AE	14 (36%)	15 (36%)
Subjects with at least one SAE	0	1 (2%)
Subjects with at least one treatment-related AE	4 (10%)	2 (5%)
Most Common Adverse Events		
Upper respiratory tract infections	3 (8%)	2 (5%)
Headache	2 (5%)	3 (7%)
Treatment Related Adverse Events		
Pruritus	2 (5%)	2 (5%)
Dandruff	1 (3%)	0
Rash pruritic	1 (3%)	0
Burning Sensation	0	1 (3%)

Results

The primary endpoint was the mean change in target area hair count between active and sham-treated subjects at week 16. The efficacy evaluable population was defined as subjects who completed at least 16 weeks of treatment, had no major protocol violations, and who were at least 80% compliant with the 10 minutes per day treatment regimen for the duration of the trial. After 16 weeks, subjects that were treated with the dual wavelength red light device and were at least 80% compliant (n=18) had a mean change of 26.3 more hairs per cm² compared to those participants who wore a sham cap, identical in appearance but received no light therapy (n=18).

Primary Endpoint @ 16 Weeks

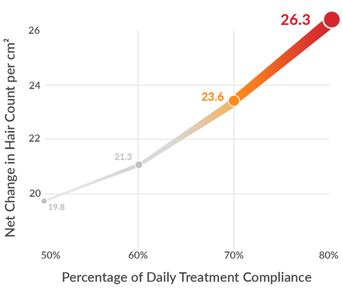




Total hair counts were obtained from computer assisted scans of digital photographs taken of a defined target area (1 cm²) centered around a tattoo located in the anterior mid area of the scalp.

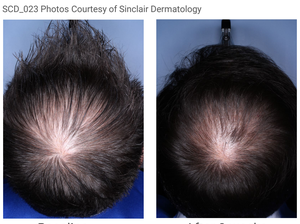
Net Change in Hair Count Based on Treatment Compliance

The Bluetooth connected mobile app is used to initiate treatment and thereby tracks daily treatment compliance in a cloud-based architecture. Compliance was tracked in deciles, where a dose dependent increase in net change in hair counts/cm² was observed with increasing daily usage of the dual wavelength device.



MALE PHOTOS

SCD_023 Photos Courtesy of Sinclair Dermatology



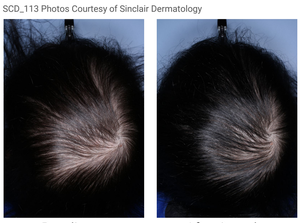
Baseline | After 8 weeks

SCD_029 Photos Courtesy of Sinclair Dermatology

Baseline | After 16 weeks

FEMALE PHOTOS

SCD_113 Photos Courtesy of Sinclair Dermatology



Baseline | After 8 weeks

PRS_102 Photos Courtesy of Premier Specialists

Baseline | After 16 weeks

Conclusion

REVIAN RED is a safe and effective alternative to chemical-based topical and prescription therapies for patients with androgenetic alopecia with results seen as early as 16 weeks.

1500-000043

This trial was sponsored by REVIAN, Inc.