ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: February 9, 2018

ClinicalTrials.gov ID: NCT03400202

Study Identification

Unique Protocol ID:	SCRIC17-PHYEYE-01
Brief Title:	Physiopathologic Aspects and Quality of Life in Participants With Eye Dark Circles
Official Title:	Eye Dark Circles: Physiopathologic Aspects and Influence on Quality of Life in Subjects of Various Ethnicities and Fitzpatrick Skin Types Utilizing Non-invasive In Vivo Instrumentation and Validated Questionnaires
Secondary IDs:	

Study Status

Record Verification:	February 2018
Overall Status:	Recruiting
Study Start:	February 2, 2018 [Actual]
Primary Completion:	December 1, 2018 [Anticipated]
Study Completion:	December 1, 2018 [Anticipated]

Sponsor/Collaborators

Sponsor:	Allergan
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	Yes
Unapproved/Uncleared Device:	No
Pediatric Postmarket Surveillance:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 12/12/2017 Board Name: Aspire IRB Board Affiliation: Central IRB Phone: 619-469-0108 Email: aspiresmtp@wcgclinical.com Address:

11491 Woodside Ave., Santee, CA 92071

Data Monitoring: No

Study Description

Brief Summary: This study will evaluate the physiopathologic characteristics of dark circles in participants with various ethnicities and Fitzpatrick Skin Types and the impact of the dark circles on the quality of life.

Detailed Description:

Conditions

Conditions: Periorbital Hyperpigmentation

Keywords:

Study Design

Study Type: Observational

Observational Study Model: Case-Control

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 100 [Anticipated]

Number of Groups/Cohorts: 4

Groups and Interventions

Groups/Cohorts	Interventions
Group A: Dark Circles None Group A includes participants with Dark Circle Severity Scale score 0 (None). Assessments of the participant's eye dark circles will be made after facial cleansing, utilizing in vivo skin imaging and quality of life questionnaires.	Device: Skin imaging Non-invasive in vivo skin imaging will be taken with the VivoSight Ox Optical Coherence Tomography (OCT). Facial cleanser Facial cleanser prior to procedures. Other Names: • SkinMedica Facial Cleanser
Group B: Dark Circles Mild Group B includes participants with Dark Circle Severity Scale score 1 to 3 (Mild). Assessments of the participant's eye dark circles will be made after facial cleansing, utilizing in vivo skin imaging and quality of life questionnaires.	Device: Skin imaging Non-invasive in vivo skin imaging will be taken with the VivoSight Ox Optical Coherence Tomography (OCT). Facial cleanser Facial cleanser prior to procedures. Other Names: • SkinMedica Facial Cleanser
Group C: Dark Circles Moderate	Device: Skin imaging

Groups/Cohorts	Interventions
Group C includes participants with Dark Circle Severity Scale score 4 to 6 (Moderate). Assessments of the participant's eye dark circles will be made after facial cleansing, utilizing in vivo skin imaging and quality of life questionnaires.	Non-invasive in vivo skin imaging will be taken with the VivoSight Ox Optical Coherence Tomography (OCT). Facial cleanser Facial cleanser prior to procedures. Other Names: • SkinMedica Facial Cleanser
Group D: Dark Circles Severe Group D includes participants with Dark Circle Severity Scale score 7 to 9 (Severe). Assessments of the participant's eye dark circles will be made after facial cleansing, utilizing in vivo skin imaging and quality of life questionnaires.	Device: Skin imaging Non-invasive in vivo skin imaging will be taken with the VivoSight Ox Optical Coherence Tomography (OCT). Facial cleanser Facial cleanser prior to procedures. Other Names: • SkinMedica Facial Cleanser

Outcome Measures

Primary Outcome Measure:

1. Dark Circles Severity Scale Score
   The investigator will access the participant's lower and upper eyelids using the Dark Circles Severity Scale where 0=None to 9=Severe (very dark circles).

   [Time Frame: Day 1]
2. Classification Type of Dark Circles Score
   The investigator will assess the lower eyelids for the following types of dark circles: Pigmented, Vascular and Shadow Effect. Each of these 3 types are graded where 0=none to 3=severe.

   [Time Frame: Day 1]
3. Age Appraisal Score
   The Age Appraisal Score consists of 7 statements. The participant rates each of these statements about the age their face looks right now using a 4-point scale where: 1=Definitely disagree (best) to 4=Definitely agree (worst) for a total possible score of 7 (best) to 28 (worst).

   [Time Frame: Day 1]
4. Age Appraisal Visual Analog Scale (VAS)
   The participant answers the question about how old they feel in relation to their current age by putting a vertical line on a horizontal line where: the far left is -15 (I look 15 years younger) to 15 (I look 15 years older) on the far right of the line. 0=I look my age.

   [Time Frame: Day 1]
5. Social Confidence Questionnaire Score
   The Social Confidence Questionnaire consists of 16 statements participants might use to describe themselves. The participant rates each of these statements with their facial appearance in mind over the previous 7 days, using a 4-point scale where: 1=Definitely disagree (worst) to 4=Definitely agree (best) for a total possible score of 16 (worst) to 64 (best).

   [Time Frame: Day 1]
6. Physiological Well-being Questionnaire Score
   The Physiological Well-being Questionnaire consists of 16 statements people might use to describe themselves. The participant rates each of these statements with their facial appearance in mind over the previous 7 days, using a 4-point scale where: 1=Definitely disagree (worst) to 4=Definitely agree (best) for a total possible score of 16 (worst) to 64 (best).

[Time Frame: Day 1]

Secondary Outcome Measure:

7. Subject Questionnaire on Dark Circles, Medical History, and Lifestyle Habits
   The Subject Questionnaire on Dark Circles, Medical History and Lifestyle Habits is a 15-item questionnaire completed by the participant.

   [Time Frame: Day 1]

8. Appraisal of Upper Eyelid Score
   The participant answers 13 questions about how much they have been bothered by their upper eyelids in the past week. Each question is answered on a 4-point scale where: 1=Not at all (best) to 4=Extremely (worst) for a possible score of 13 (best) to 52 (worst).

   [Time Frame: Day 1]

9. Appraisal of Lower Eyelid
   The participant answers 16 questions about how much they have been bothered by the area under their lower eyelids in the past week. Each question is answered on a 4-point scale where: 1=Not at all (best) to 4=Extremely (worst) for a total possible score of 16 (best) to 64 (worst).

   [Time Frame: Day 1]

10. Pittsburgh Insomnia Rating Scale (PIRS) Score
    The PIRS is a 20-item questionnaire completed by the participant assessing sleep over the previous 7 days. Scores range from 0 (best) to 60 (worst), with scores above 20 indicating insomnia.

    [Time Frame: Day 1]

Eligibility

Study Population:	Participants at a Clinical Research Center.
Sampling Method:	Probability Sample
Minimum Age:	25 Years
Maximum Age:	50 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria:

- Participants with Fitzpatrick skin type I-VI
- Willingness to not wear any eye makeup on the day of the study visit prior to the study visit appointment
- Willingness to cleanse the face and remove all makeup at least 15 minutes prior to each scheduled clinic visit
- Willingness to have facial exams, skin instrumentation measurements, and digital photos performed on the face.

Exclusion Criteria:

- Individuals with active symptoms of allergy, cold sore or warts, active psoriasis or eczema, rosacea, sunburn, open wounds, neurotic excoriations, excessive scarring, tattoos, or other skin conditions in the test area
- Uncontrolled disease such as diabetes, hypertension, hyper or hypo-thyroidism, active hepatitis, immune deficiency, or autoimmune
- Individuals who have a pre-existing or dormant dermatologic condition (e.g. history of severe psoriasis, atopic dermatitis, rosacea, skin cancer, etc.)

- Individuals who have had a blepharoplasty procedure or any other surgery in proximity or affecting the test area
- Individuals with recent procedures/surgeries (less than 6 months) on the eye bulb
- Individuals with permanent makeup around the eye area
- Chemical peel, microdermabrasion, microneedling, or dermaplaning in the previous 4 weeks
- Latisse, Revitalash, or other lash enhancement stimulators in the previous 1 month
- Retin-A®, Retin-A Micro®, Renova®, Avita®, Tazorac®, Avage® or Differin® or other similar prescription drugs within the previous 3 months
- Cosmetic injections (filler and/or toxins, i.e.Juvederm, Radiesse, Botox, etc.), non- ablative laser or fractional laser resurfacing in the previous 12 months
- Accutane® or other oral retinoid, Ablative procedures (i.e. laser, chemical) in the previous 12 months
- Individuals who have any planned surgeries or procedures during the study.

Contacts/Locations

Central Contact Person: Clinical Trials Registry Team
Telephone: 877-277-8566
Email: IR-CTRegistration@Allergan.com

Central Contact Backup:

Study Officials: Lisa Goberdhan
Study Chair
Allergan

Locations: United States, California
SkinMedica Clinical Research and Innovation Center
[Recruiting]
Irvine, California, United States, 92612

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information: