ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

Version Spots free cream in the Treatment of Mild to Moderate Melasma in Greek Women

This study was to evaluate the efficacy and safety of Version Spots Free Cream (Oligopeptide-34, SabiWhite™, Arbutin, Kojic acid dipalmitate and sunscreen filters) when used in Subjects diagnosed with mild to moderate melasma during a 12 week treatment period.

Condition	Intervention	Phase
Melasma	Drug: Version Spots Free Cream (Oligopeptide-34, SabiWhite™, Arbutin, Kojic acid dipalmitate and sunscreen filters) Vehicle: Version moisturizing cream	Phase IV

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Single Blinded, Placebo controlled, Randomized, Clinical Efficacy Study in Subjects with Melasma using Version Spots Free Cream

Primary Outcome Measures:

- Number of Participants Who Were a Success or Failure With Regards to Melasma Severity at Week 12 as Evaluated Using the modified MASI score

Secondary Outcome Measures:

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

- Number of Participants Showing Success or Failure in Improvement of Melasma at Week 6, 8 and 10 Using the Investigator's Evaluation of Improvement
- Number of Participants Showing Success or Failure in Improvement of Melasma at Week 6, 8 and 10 Using the Subject's Evaluation of Improvement
- Number of Participants Showing Success or Failure in Improvement of Melasma at Week 12 Using the Subject's

Enrollment: 36

Study Start Date: October 2011

Study Completion Date: March 2012

Primary Completion Date: April 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Version Spots Free Cream	Drug: Oligopeptide-34, SabiWhite™, Arbutin, Kojic acid dipalmitate and sunscreen filters Applied once daily at bedtime on all affected areas of the face; this was an open label, evaluator-blinded randomized, placebo controlled study with 1:1 randomization assignment
VERSION Moisturizing Cream as Inactive Control	Drug: VERSION Moisturizing Cream as Inactive Control. Applied once daily at bedtime on the face of half of the patients

Detailed Description:

Same as above.

Eligibility

Ages Eligible for Study: 18 Years to 63 Years
Genders Eligible for Study: Females

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

Criteria

Inclusion Criteria:

- Subjects diagnosed with mild to moderate melasma on the face (Investigator's Global Assessment (IGA) at baseline must be 3 or 4 and modified MASI score of 6-18)
- Fitzpatrick's skin types I to IV
- Signed informed consent
- Given verbal agreement on protection from UV light during treatment by the usage of physical barriers (umbrellas, caps, hats, etc).
- Patients who have not done any treatment for melasma in the 3 months preceding the study
- Patients with good mental and physical health;
- Patients who agree with the purposes of the study

Exclusion Criteria:

- Subjects with a diagnosis of skin cancer (Basal Cell Carcinoma (BCC), Squamous Cell Carcinoma (SCC), Melanoma) in the areas to be treated
- Subjects with prior facial Intense Pulsed Light (IPL), resurfacing, deep or chemical peels within 6 months of the date of study entry
- Subject has initiated treatment with hormones including estrogen, progesterone and/or oral contraceptives within 3 months of study entry, or who intend to discontinue hormonal therapy during the study
- Fitzpatrick's skin types V and VI
- Treatment with steroids within the duration of the study
- Oral contraception within the duration of the study
- Usage of other cosmetics within the duration of study
- Treatment with Clofazimine within the duration of the study
- Patients with skin diseases other than melasma, which interfere in clinical evaluation as hemangiomas and queloides;
- Patients with known hypesensitivity to any of the ingredients
- Patients who are pregnant or breastfeeding

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

Locations

Thessaloniki, Greece

1st Department of Dermatology/Venereology of Aristotle University, Thessaloniki, Greece

Sponsor
Version Derma
.

Primary Investigator
Prof. Demetrios Ioannides, MD, PhD

Detailed Description:

Patients have been randomized and allocated in concealed manner to one of the two treatment arms: Version Spots Free Cream and inactive control (Version hydrating cream)

Patients randomized to the Version Spots Free Cream or to the inactive control will receive treatment once daily (bedtime application) for a period of 12 weeks.

An efficacy study of Version Spots Free Cream against facial melasma

Background: Melasma is a common disorder of hyperpigmentation characterized by brown or gray-brown patches on sun-exposed facial areas causing significant cosmetic. Available topical treatments are not satisfactory requiring prolonged application with substantial relapse rates.

Aim: The objective of this 12-week study was to assess the therapeutic effect of Version Spot Free Cream on mild to moderate facial melasma in Greek women not suffering from underlying hyperpigmantation disorders.

Methods: This was an open label, evaluator-blinded, vehicle controlled study of 12 weeks duration. Thirty Six (36) female patients with facial melasma were recruited in the study. The minimum modified melasma area and severity index (modified MASI) required was six(6). The two creams involved with 1:1 split were the Version Spots

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

Free Cream and as the active vehicle cream the moisturizing Version Cream had been chosen. Treatment has been applied on a once daily basis at night for a period of 12 weeks. Evaluator-blinded study assessments were conducted at baseline and weeks 4, 8, 10 and 12. At the baseline visit, following a detailed history and clinical examination under natural light, modified MASI was calculated and color photographs were taken on 15 out of the 36 patients. Treatment was initiated randomly with one of the two preparations. Patients were advised to avoid sun exposure and apply the cream at night, while visits for efficacy assessment were planed after the initial 4 weeks, fortnightly for the remaining 8 weeks duration of the study. All assessments were performed by the same blinded investigator in order to avoid any bias and subjective evaluations.

Results: Objective response to treatment evaluated by reduction in modified MASI scoring after 12 weeks was by 68% reduction in the Version Spots Free cream group vs 10% reduction in the vehicle group. Subjective response, as graded by the patient, showed good or very good response in 70% in the active drug group and 15% in the vehicle group after the 12 weeks period. No relation of treatment response to age and duration of melasma could be established in this study.

Conclusions: Results from the active treatment arm demonstrated that at weeks 4 and 8 treatment with Version Spots Free cream resulted in a reduction of modified MASI score and Investigator global assessment of response to treatment while at week 12 it continued to demonstrate sustained improvements. There was a notable reduction of at least 6 points in the modified MASI score in the 15 out of the 18 subject that had been randomized to the study drug arm, while in the placebo arm such reduction was seen only in 2 patient. Due to the fact that this cream does not contain active ingredients that have limitations on the duration of treatment, avoidance of melasma relapse could be achieved by maintenance treatment for longer periods. There are hardly any major side effects, and tolerability issues seen with the cream and therefore this novel product could be considered when weighing long-term treatment options.

References

1. Kar HK, Gupta L, Chauhan A. A comparative study on efficacy of high and low fluence Q-switched Nd:YAG laser and glycolic acid peel in melasma. Indian J Dermatol Venereol Leprol. 2012; 78(2):165-71

2. Farshi S. Comparative study of therapeutic effects of 20% azelaic acid and hydroquinone 4% cream in the treatment of melasma. J Cosmet Dermatol. 2011 Dec;10(4):282-7

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΟΝΙΚΗΣ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ
ΤΟΜΕΑΣ ΠΑΘΟΛΟΓΙΑΣ
Α΄ ΚΛΙΝΙΚΗ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ
Διευθυντής : Καθηγητής ΔΗΜΗΤΡΙΟΣ ΙΩΑΝΝΙΔΗΣ

Πληροφορίες :
Τηλ. 2313308822, 2310992262
e- mail : dem@auth.gr
Κτίριο:ΝΟΣΟΚΟΜΕΙΟ ΑΦΡΟΔΙΣΙΩΝ ΚΑΙ ΔΕΡΜΑΤΙΚΩΝ ΝΟΣΗΜΑΤΩΝ

3. Tourlaki A, Galimberti M, Pellacani G, Bencini PL. Combination of fractional erbium-glass laser and topical therapy in melasma resistant to triple-combination cream. J Dermatolog Treat. 2012 Mar 3. [Epub ahead of print]

4. 10: Hong SP, Han SS, Choi SJ, Kim MS, Won CH, Lee MW, Choi JH, Moon KC, Kim YJ, Chang SE. Split-face comparative study of 1550 nm fractional photothermolysis and trichloroacetic acid 15% chemical peeling for facial melasma in Asian skin. J Cosmet Laser Ther. 2012;14(2):81-6

5. 11: Sobhi RM, Sobhi AM. A single-blinded comparative study between the use of glycolic acid 70% peel and the use of topical nanosome vitamin C iontophoresis in the treatment of melasma. J Cosmet Dermatol. 2012; 11(1):65-71

6. Kauvar AN. Successful treatment of melasma using a combination of microdermabrasion and Q-switched Nd:YAG lasers. Lasers Surg Med. 2012 Feb;44:117-24

7. Na JI, Choi SY, Yang SH, Choi HR, Kang HY, Park KC. Effect of tranexamic acid on melasma: a clinical trial with histological evaluation. JEADV 2012 Feb; 13