DOUBLE-BLIND PLACEBO CONTROLLED TRIAL TO INVESTIGATE THE USE OF PLE (*Polypodium leucotomos* Extract) IN THE MANAGEMENT OF MELASMA

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INTRODUCTION →

Melasma is a pigmentary disorder common amongst Asian population. Solar radiation is the most important trigger factor. *Polypodium leucotomos* Extract (PLE) has scientifically demonstrated photoprotective properties due to its antioxidant, antiinflammatory and DNA-repair abilities.

OBJECTIVE →

To demonstrate the efficacy of PLE in improving the outcomes of melasma standard treatment

METHODS

Randomized, double-blind, placebo-controlled study.

33 women:

- **Age:** 25-55
- **Skin types** III and IV

Hydroquinone 4% + Sunscreen SPF50

GOLD STANDARD TREATMENT

+

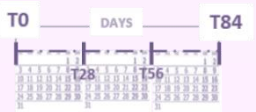
Group PLE — N= 16

Group PLACEBO — N= 17

The endpoints for efficacy were measured:

1. **Quantitatively**
   - Modified MASI score
   - Colorimetry
2. **Qualitatively**
   - Patient Satisfaction
   - Quality of Life Questionnaire

VISITS CALENDAR

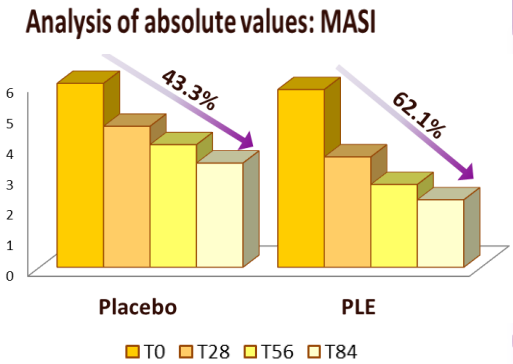


RESULTS

The percentage of **mMASI reduction** improved in both groups at T84 compared to baseline; however, a stronger reduction was observed in PLE group (54.9% Vs. 44.4%), only reaching statistical significance at T56 due to limited cohort and study duration (p=0.027).

Statistical significance was obtained for **absolute mMASI values** between groups: at T28, PLE group was already 21.7% better compared to placebo (p=0.053), 32.5% at T56 (p=0.014) and 35.3% at T84 (p=0.041).

MelasQoL values were reduced in both groups after the treatment, as it was expected given that both received the treatment with hydroquinone and sunscreen. However, the global trend in the PLE group was a greater and quicker improvement of melasma compared to the placebo group, specially at T28, when MelasQol improved by 20.0% and 12.5%, respectively.



Iconography from a patient of PLE group.

CONCLUSIONS

The beneficious effect of PLE as an adjuvant therapy in melasma management has been demonstrated. The results of this pilot study would be the precedent for subsequent clinical trials.

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