# Randomized study to assess the efficacy of a facial cosmetic product with nanoencapsulated cysteamine in women presenting melasma

**Poster 472**

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## Introduction:

Melasma is a common and persistent pigmentary disease that particularly affects women during their reproductive period [1-2]. The chronicity of the disease and the involvement of visible areas during working age generates a great negative impact on the quality of life of affected individuals.[3]

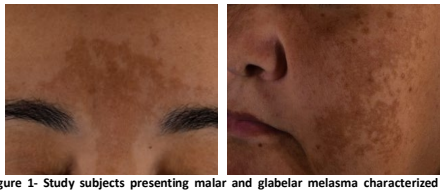

**Figure 1- Study subjects presenting malar and glabelar melasma characterized by symmetrical hyperpigmented macules or patches with irregular borders, most often distributed on the face.**

There are several therapeutic options for the treatment of melasma that act on different stages of melanogenesis. The vast majority of effective depigmenting agents are tyrosinase inhibitors, of which hydroquinone is the most studied and most effective drug. However, there is concern about its tolerability and its prolonged use due to the risk of adverse events such as exogenous ochronosis. Therefore, there is an interest in seeking other depigmenting agents in the treatment of melasma. [4-5]

## Materials & Methods:

This single-blind, randomized and comparative study of a cosmetic product with nano encapsulated cysteamine, a promising and more tolerable option, and sunscreen SPF 60 versus sunscreen SPF 60 alone was conducted to investigate the efficacy in improving melasma and improving the quality of life of subjects.

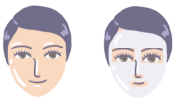


**Figure 2- Control group was oriented to apply sunscreen SPF 60 twice a day on entire face for 84 days. Treatment group was oriented to apply the IP on entire face every night and apply sunscreen SPF 60 twice a day for 84 days.**

**Table 1- Subject's characteristics panel**

| | Investigational group (IP + sunscreen SPF 60) | | Control group (sunscreen SPF 60) | |
|---|---|---|---|---|
| **Mean age (years)** | 45 | | 44 | |
| **Female** | 24 | 100,0% | 19 | 100,0% |
| **Phototype III (Fitzpatrick)** | 6 | 25,0% | 3 | 15,8% |
| **Phototype IV(Fitzpatrick)** | 13 | 54,2% | 8 | 42,1% |
| **Phototype V (Fitzpatrick)** | 5 | 20,8% | 8 | 42,1% |
| **Presenting Melasma** | 24 | 100,0% | 19 | 100,0% |
| **Chronic non-smokers** | 24 | 100,0% | 19 | 100,0% |

**Table 2- Study flowchart representing the kinetics and study procedures**

| Study procedures | D0 | D28 | D56 | D84 |
|---|---|---|---|---|
| Dermatological evaluation (melasma hyperpigmentation intensity, area affected by melasma, skin tone uniformity, skin hydration, softness, brightness and oiliness). | X | | X | X |
| MelasQoL questionnaire (impact of melasma on their quality of life) | X | X | X | X |
| Color Face standardized clinical pictures | X | | | X |
| Confocal Reflecting Microscopy (characteristics of the epidermis, dermo-epidermal junction, and dermis) | X | | | X |
| Possible local intolerance and adverse event evaluation | | X | X | X |

## Results & Discussion:

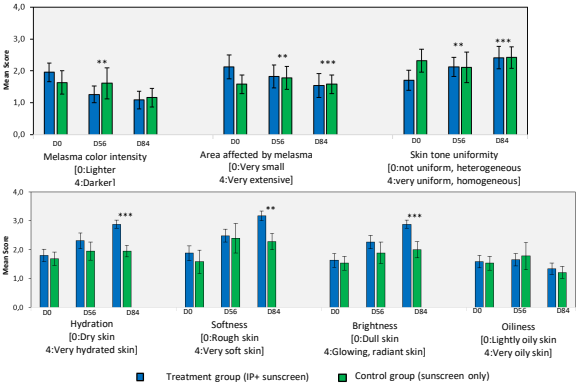


**Figure 3- Dermatological evaluation of skin parameters by group, Error bars: 95% CI, **p value≤0.010, ***p value≤0.001**

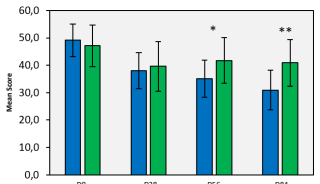


**Figure 4- MelasQoL questionnaire by group, Error bars: 95% CI, *p value≤0.050, **p value≤0.010**

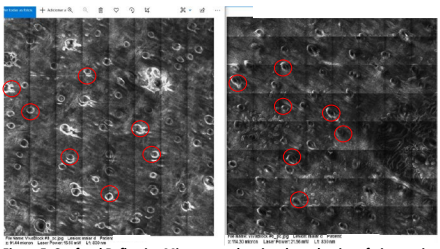

**Figure 5- Confocal Reflecting Microscopy showing the reduction of pigment in skin keratinocytes. Subject allocated in treatment group. (Left- D0 and Right- D84) (red circles marking the reduction of white reflection that represents pigment)**

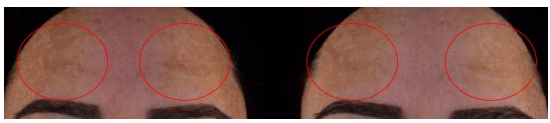

**Figure 6- Color Face standardized clinical pictures. Subject allocated in treatment group. (Left- D0 and Right- D84) (red circles representing the hyperpigmentation improvement)**

During the study, it was possible to observe on the comparison between two groups, a significant improvement of melasma hyperpigmentation intensity after 56 days (p value = 0.004) using investigational product plus sunscreen SPF 60 and a significant improvement of the area affected by melasma (p value <0.001), skin tone uniformity (p value = 0.001), skin hydration (p value <0.001), softness (p value =0.006) and brightness (p value <0.001) after 84 days using investigational product plus sunscreen SPF 60 when compared to the group sunscreen SPF 60 only **(Figure 3)**.
MelasQol results revealed a significant difference (p value = 0.003) in the impact of melasma on quality of life after 84 days after IP plus sunscreen SPF 60 use when compared to the group sunscreen SPF 60 only **(Figure 4)**.
Reflective confocal microscopy results showed pigment reduction in keratinocytes in the epidermis, around adnexal structures and at the dermal-epidermal junction **(Figure 5)**. ColorFace standardized pictures contributed with illustrative images of hyperpigmentation improvement **(Figure 6)**
No subject presented any medically relevant local intolerance that occurred at the assessment site (face) due product application.

## Conclusions:

Nano encapsulated cysteamine improves hyperpigmentation intensity, area affected by melasma and individual's quality of life when compared to the control group, with a good tolerability profile, and is an efficient alternative to depigmenting agents such as tyrosinase inhibitors.

## References:

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