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Conclusions of the “International Multicentre Trial of applying the innovated Melanil® cream CATALYSIS S. L. Madrid in patients with chloasma-melasma and other types of pigmentations (lentigo solaris, lentigo senilis) on the face, neck and décolleté, and hand dorsae”

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CATALYSIS, S.L.

**Conclusions of the pilot trial to verify the effects of applying
MELANIL[®] cream, CATALYSIS, S. L., Madrid,
in patients with chloasma or melasma and other pigmentations such as lentigo
solaris or lentigo senilis localised on the face, neck and décolleté**

Type IV double blind placebo controlled trial with post-registration monitoring and continuous inclusion of patients into the trial according to set criteria

to verify the efficacy and tolerability of applying Melanil[®] cream, a product of CATALYSIS S.L. Madrid, in patients with hyperpigmentations, namely of chloasma or melasma type, or lentigo solaris localised on the face and assess the differences in tolerability and depigmentation effect in individual patients

Number of Patients:	80
Number of applications:	twice a day
Application duration:	min. 42 days (6 weeks), max. 98 days (14 weeks)
Application information:	given by the therapist both orally and in writing
Documentation:	working protocol, tables
Basic laboratory screening:	performed in every patient
Basic examination:	dermatoscopy, Wood's lamp, Multi Skin Test Center[®]
Photodocumentation:	pictures taken 2 – 3 times in every patient
Special examination:	histology and micro photography in selected patients (Žilina Centre)
Recommended daily hygiene:	non irritating preparations with no influence on the therapy process

Inclusion criteria

- Chloasma – melasma faciei
 - 1. ***Centrofacial type*** – affecting cheeks, the skin above the upper lip, nose and chin
 - 2. ***Cheek type*** – affecting cheeks and nose, only
 - 3. ***Mandibular type*** – affecting ramus mandibularis
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- Aging or damaged skin on the face, neck and décolleté with lentigo solaris or senilis
 - Outpatient status

- Age: 20 – 60 years
- Voluntary participation in the trial
- Written patient consent form confirmation
- One-time participation in the trial

Exclusion criteria

Specific exclusion criteria

- Usage of contraceptives
- Known allergy to the tested preparation
- Disease focus infection manifestations
(superinfection requiring therapy)
- Immunosuppressive therapy
- Cancer
- Malignancies
- Employment of other drug/s and /or preparation/s in therapy

General exclusion criteria:

- Alcohol and drug abuse
- Painkiller abuse
- Participation in another clinical trial within the past 30 days
- Simultaneous participation in any other clinical trial
- Other reasons excluding the patient from the trial
- Restricted ability of the patient to follow therapy instructions
- Other physical or mental disorders disturbing the trial plan
- Possible consent withdrawal, presumed patient unreliability

CONCLUSIONS

- **4 trial participants (10%)** excellent improvement with 80-100% reduction in pigmentations excellent aesthetic and cosmetic effect
- **19 trial participants (48%)** satisfactory improvement with 70% reduction in pigmentations satisfactory aesthetic and cosmetic effect
- **14 trial participants (35%)** insignificant improvement with 30% reduction in pigmentations
- **3 trial participants (8%)** dissatisfactory condition with no changes in pigmentation

MELANIL[®] cream, produced by the company CATALYSIS, S.L., fully meets all the declared usage objectives. The cream represents a high quality preparation used to treat skin with pigmentations including melasma, chloasma, aging skin on the face, neck, and décolleté affected by various external influences, or skin affected by lentigo solaris, or lentigo senilis.

MELANIL[®] is produced using a unique technology including molecular activation, which increases the activity of active ingredients 20 to 100 times. The chemical composition remains unchanged, only the bioactivity of the product is increased.

The efficacy of MELANIL[®] cream, Catalysis S. L. Madrid was verified in a pilot trial carried out in 2006 - 2007.

In order to verify the indication range and the declared effects it was necessary to assess the efficacy and tolerability of MELANIL[®] cream, CATALYSIS S. L. Madrid in comparison with a group of trial participants applying placebo (to a contralateral side of the face, the other hand dorsum) in randomly elected centres.

The results obtained proved the efficacy of MELANIL[®] cream, Catalysis S. L. Madrid and determined that the product is comparable with other renowned depigmenting products used in practice. As is the case in other products, the depigmenting effect of MELANIL[®] cream is temporary. In sensitive patients it is necessary to apply sunscreen to sun exposed areas with high SPF.

No undesired or adverse reactions appeared after the application of MELANIL[®] cream or placebo, which is a very positive finding. This fact proves that the formula of the preparation is well elaborated (placebo contains no active ingredients, but the texture is the same), the product may thus be used by sensitive patients or patients with allergies. The trial participants appreciated the texture of the preparation as well as the pleasant scent of MELANIL[®] cream.

The trial was performed in winter months, when UV exposure is less harmful, despite that, all trial participants were instructed to use sunscreen with high SPF (Anthelios 50+), which they were applying during the whole trial period on top of Melanil[®] cream, since Melanil[®] cream, Catalysis S. L. Madrid has not enough UV filters.

During the trial other therapeutic modalities were eliminated (such as microdermabrasion, macrodermabrasion and hydrabrasion, chemical peels), which could influence the assessment of effects of the tested preparation.

Only in Centre 03 there were 3 participants in which microdermabrasion was performed prior to trial inclusion. Thanks to this combined technique (**microdermabrasion + MELANIL[®] cream**) **a more significant aesthetic effect was observed in those patients and a better final result.**

The investigators suggest that the application instructions of MELANIL[®] cream should highlight the possibility of using combined techniques (microdermabrasion, hydrabrasion, peels) before the therapy with MELANIL[®] cream, or during the application of the depigmenting preparation. The frequency of using combined techniques is very much dependant on the expertise of the therapist or the equipment of the clinic recommending the preparation.

MELANIL[®] cream, Catalysis Madrid provides the declared effects. **The results obtained within the presented international multicentre trial are promising in adequate application in many patients.**