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RESEARCH ARTICLE

An Open Label, Non Comparative, Non-randomized, Pilot study to see the efficacy and safety of anti wrinkle cream in the treatment of facial skin wrinkles

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Abstract

Background: Wrinkles are the clinical manifestation of 'coetaneous aging' and factors associated with wrinkles could be 'intrinsic' and 'extrinsic'. The "Anti-Wrinkle cream" is a poly-herbal formulation recommended for the management of skin wrinkling.

Aims and objectives: This study was planned to evaluate the efficacy and safety of the "Anti-Wrinkle cream" in the management of facial skin wrinkles.

Material and methods: After confirming eligibility, 30 patients were enrolled in the study and each of the patients was provided with Anti-Wrinkle cream. The regimen of Anti-Wrinkle cream was followed in each of the patient for study duration of 06 weeks.This was conducted in accordance to the ICH-GCP guidelines with approval from Independent Ethics Committee. Written Informed consent was obtained from these patients after a thorough explanation of the study.Patients with wrinkles on the face and neck were included in the study. These patients agreed to restrain from prolonged exposure to the sun for the length of the study.

Results and discussion: The patients were assessed for Modified Fitzpatrick Wrinkle Scale (MFWS), improvement in 'Quality of Life', 'Patient Satisfaction Questionnaire', Physician's and Patient Global Assessment Grade for improvement in wrinkles and Photographic assessment at baseline, 3 weeks and 6 weeks.The average MFWS (Modified Fitzpatrick Wrinkle Scale) at baseline (Visit 1) was 2.1 which was reduced to 1.6 after 3 weeks of treatment (Visit 2) and further reduced to 1.2 after 6 weeks of treatment (Visit 3) with Anti-Wrinkle cream.The Physician's and Patient's global assessment also showed improvement in wrinkles at visit 2 and visit 3.

Conclusion: In our study it was noted that, Anti-Wrinkle cream appears to be effective and safer alternative with 6 weeks of therapy. In terms of efficacy, there was a moderate to significant reduction in the MFWS score for the treatment groups, brought about with 6 weeks of treatment.

Limitations and recommendation: This was a pilot study conducted only on 50 subjects with only single study centre furthermore comprehensive and detailed multi centric study can be done to evaluate the effectiveness of "Anti-Wrinkle cream"..

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Introduction:

Aging of the skin is the result of continuous "wear and tear" processes, which damage cellular DNA and proteins. Aging has been classified into 2 distinct types, viz. "chronological skin aging" and "photoaging" and both types have distinct clinical and histological features. Chronological skin aging is a universal and inevitable process, characterized primarily by physiologic alterations in skin function. In chronological skin aging, keratinocytes are terminally unable to form a functional stratum corneum, and the rate of formation of neutral lipids (which contribute to the barrier functions) gets slowed, resulting in dry, pale skin with fine wrinkles. In contrast, photoaging results from the UV rays of sunlight, and the damage becomes apparent in sun-exposed skin. Characteristics of photoaging are dry and sallow skin, displaying fine wrinkles as well as deep furrows, resulting from the disorganization of epidermal and dermal components associated with elastosis and helio dermatitis[1].(Lapie`re CM. 1990).
Wrinkles are the clinical manifestation of 'cutaneous aging' and factors associated with wrinkles could be 'intrinsic' and 'extrinsic'[1].(Lapie`re CM. 1990). Intrinsic skin aging is determined largely by genetics and occurs in spite of the individual's environment. Clinically, intrinsic skin aging manifests by signs such as increased dryness, wrinkles, and skin thinning. Photoageing is the superposition of chronicultraviolet (UV)-induced damage on intrinsic ageing and accounts for most age-associated changes in skin appearance[2].(Yaar M et al. 2007) Manifestations of photoaging include superficial and deep wrinkles, development of a leathery texture, skin roughness, atrophy and dys pigmentation.

Extrinsic skin ageing primarily arises from UV-light exposure. Approximately 80% of facial skin ageing is attributed to UV-exposure[3].(Uitto J. 1997) Most of the photoaging effects occur by age 20. The amount of damage to the skin caused by the sun is determined by the total amount of radiation exposure and the person's pigment protection. Changes in the epidermis caused by the sun include thinning of the epidermis and expression of epidermal lesions such as actinic keratoses, basal cell carcinomas, and squamous cell carcinomas. In the dermis, solar effects cause collagen to break down at a higher rate than seen with just chronologic aging. The dermis and hypodermis become atrophied during ageing, with a reduction of collagen[4,5],(Aubinie`re E 1985, Warren R, Kligman AM, Montagna W et al. 1991) of certain glycosaminoglycans (GAG)[6-9] (Fleischmajer R, Perlish JS, Bashey RI et al.1972, Smith JG 1962, Smith FG et al. 1965, Willen MD, Sorrell IM, Lekan CC et al.1991) and of the adipose tissue of the hypodermis[10].(Elnekave FL. et al 1989) These reductions lead to wrinkle formation. On the otherhand, elastic tissue hypertrophy produces huge amounts of elastotic material, which increases the magnitude of the wrinkles[11-13].(Bouissou H et al. 1987, Tsuji T et al. 1986, Wright ET et al. 1965) With the advent of solar elastosis matrix metalloproteinases are produced in large quantities.

The most critical step in the treatment of wrinkles is sun avoidance and sunscreen use. Prevention and progression of wrinkles can be achieved by usage of a broad spectrum sunscreen regularly, about 20 to30 minutes before sun exposure in addition to maintaining the moisture balance of the skin. Cosmetic active molecules from various sources with complementary biological properties for optimum effectiveness for effective management of wrinkles are a current trend in antiaging. With recent advances in pathophysiologic understanding of aging processes we know that hormonal profile, oxidative stress and inflammatory insults are major contributors. According to the free radical theory of ageing, reactive oxygen species(ROS), primarily arising from oxidative cell metabolism, play a major role in both chronological ageing and Photoaging[14].(E. Kohl et al. 2011) Oxidative stress and inflammation in the skin can result from both normal and pathological reactions and whatever the cause, both the process has a big influence on skin ageing. There are effective ways of modulating these mechanisms with a combination of selected commercially available actives formulated in a serum. The cosmetic active molecules are derived from vegetable, marine, peptides, and biotechnological sources with complementary biological properties for optimum effectiveness.
The "Anti-Wrinkle cream" is a polyherbal formulation recommended for the management of skin wrinkling, and it contains the extracts of Asparagus racemosus , Aloe barbadensis, Vitis vinifera, Lens culinaris, Curcuma longa, Glycyrrhiza glabra. This study was planned to evaluate the efficacy and safety of the "Anti-Wrinkle cream" in the management of facial skin wrinkles.

Aims and Objectives:

To study product performance in reduction in number and depth of facial wrinkles, fine lines, nasolabial fold and crow's feet in comparison to baseline by following parameters:

- Dermatologist's assessment
- Subject's self assessment

To study product performance in reduction of facial wrinkles in comparison to baseline by evaluating the wrinkles by the assessment scales.
Assessment for adverse events.

Key inclusion and exclusion criteria:

Healthy males and females aged between 30 years and 65years with a clinical diagnosis of: moderatevisible fine lines and wrinkles in peri orbital area (Crow's feet) and mild to moderate naso labial fold; willing to give informed consent and comply with protocol were included in the study.

Un cooperative subjects; those having significant skin diseases; pregnant and lactating females; those having severe photoaging, history of intense sun exposure, having allergic response to any cosmetic product were excluded from the study.

Materials and Methods:

This was an open labelled, prospective, single centre study was conducted in female patients with wrinkles on face and neck.After confirming eligibility, 30 male and female patients were enrolled in the study and each of the patients was provided with Anti-Wrinkle cream. The Anti-Wrinkle cream was applied twice daily in all the subjects. The regimen of Anti-Wrinkle cream was followed in each of the patient for study duration of 06 weeks.This was conducted in accordance to the ICH-GCP guidelines with approval from Independent Ethics Committee. Written Informed consent was obtained from these patients after a thorough explanation of the study.These patients agreed to restrain from prolonged exposure to the sun for the length of the study.

Patient assessment will be done at Baseline, end of 03 weeks and 06 weeks of treatment period. At the first visit (Baseline) a detailed history will be taken, examination will be done . During the 2nd visit (end of 03 weeks) and 3rd visit (end of 06 weeks), the assessment for efficacy and safety will be done.

For assessment of efficacy, Modified Fitzpatrick Wrinkle Scale (MFWS) were evaluated.

Modified Fitzpatrick Wrinkle Scale (MFWS Scale)

Score	Assessment
0	No wrinkle. No visible wrinkle; continuous skin line;
0.5	Very shallow yet visible wrinkle;
1	Fine wrinkle. Visible wrinkle and slight indentation;
1.5	Visible wrinkle and clear indentation. <1mm wrinkle depth;
2	Moderate wrinkle. Clearly visible wrinkle, 1to2mm wrinkle depth;
2.5	Prominent and visible wrinkle. > 2mm and < 3mm wrinkle depth;
3	Deep wrinkle. Deep and furrow wrinkle; >3mm wrinkle depth.

The improvement in 'Quality of Life' was assessed through a questionnaire namely, Did you notice any beneficial change in face during period of application of product?; Does your face appear more youthful now than before you started using the product?; How family, friends and people at work evaluated results? Would you like to continue the treatment?; Would you recommend the treatment to others? Was subjectively assessed by the Physician at Visit 2 and 3 and graded accordingly as Grade 1: Very Unsatisfied; Grade 2: Unsatisfied; Grade 3: Satisfied; and Grade 4: Very satisfied.

Similarly the patient rated the response through 'Patient Satisfaction Questionnaire' namely, Overall Satisfaction, Improvement in skin tone and complexion, Improvement in firmness of the skin, Moisturizing effect, Pleasant to Use and Rating as compared to previously used anti-wrinkle products (if any), as Average (Grade 1), Good (Grade 2), Very Good (Grade 3) and Excellent (Grade 4) on Visit 2 and 3.

Physician's and Patient's Global Assessment Grade for improvement in wrinkles were graded as Grade 0: Worse; Grade 1: No Change; Grade 2: Slightly Improved; Grade 3: Improved; Grade 4: Much Improved.

Results:

The average MFWS (Modified Fitzpatrick Wrinkle Scale) at baseline (Visit 1) was 2.1 which was reduced to 1.6 after 3 weeks of treatment (Visit 2) and further reduced to 1.2 after 6 weeks of treatment (Visit 3) with Anti-Wrinkle cream as shown in figure 1.

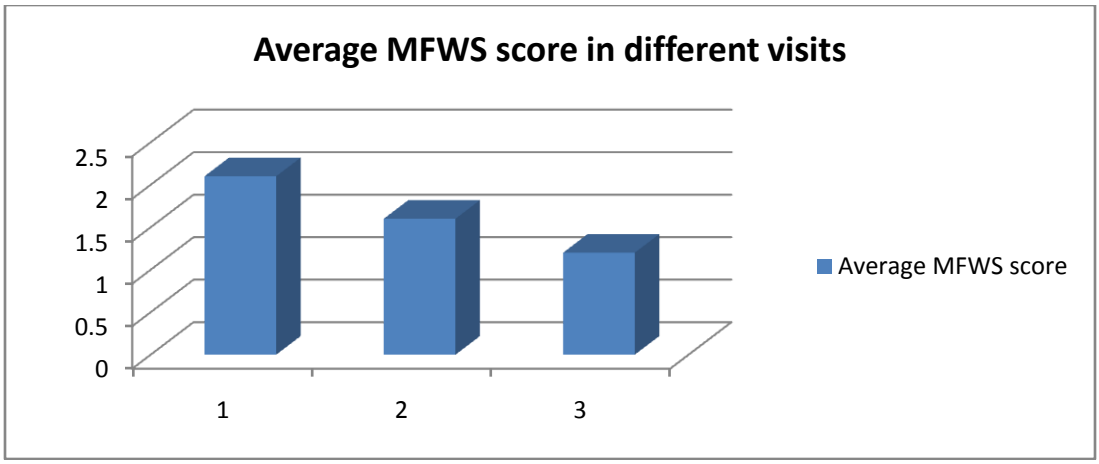

Figure 1: Showing average MFWS score in different visits.

Visit	Average MFWS score	Physician assessment	Patient assessment	Quality of life	Patient satisfaction
1(Baseline)	2.1	0.9	1.0	0	0
2(3 weeks)	1.6	1.5	1.4	2.5	2
3(6 weeks)	1.2	2.3	2.1	3.1	2.5

The Physician's and Patient's global assessment showed improvement in wrinkles at visit 2 and visit 3, as shown in figure 2. Average grade for Physician's global assessment improved from 0.9 at baseline to 2.3 at the end of 6 weeks treatment. Patient's global assessment also showed similar grades of improved from 1 at baseline to 2.1 at the end of treatment.

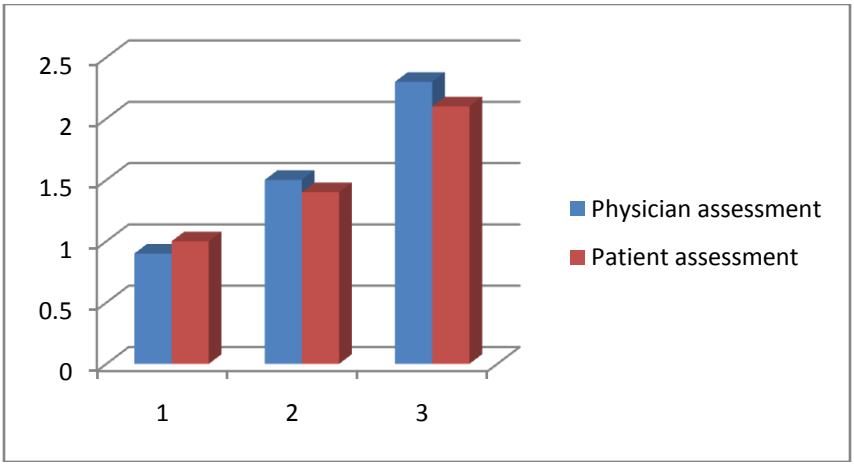

Figure 2: Physician and Patient global assessment at each visit.

There was an overall improvement in 'Quality of Life' in terms of improvement in the wrinkles at the end of 3 weeks (Grade 2.5) and 6 weeks (Grade 3.1), as shown in figure 3. All the patients responded that they would like to continue the treatment and would recommend the treatment to others. The overall 'Patient Satisfaction' was found to be good at the end of 3 weeks (Grade 2) and 6 weeks of treatment (Grade 2.5), as shown in figure 3.

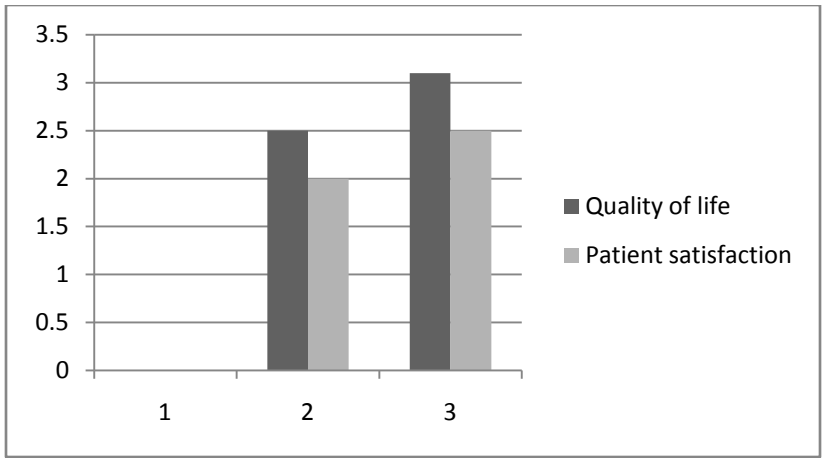

Figure 3: Quality of Life & Patient Satisfaction Questionnaire at each visit.

Discussion:

Great advances have been made to understand photoaging and the processes underlying photoaging in the last decade. The trend toward integration of multiple actives covering all mechanistic aspects of skin ageing process. This research has led to development of safer and more effective anti-aging products. The results of this study show that Anti-Wrinkle cream has a good potential for treatment of wrinkles. The better results could be because of targeting different steps of photoaging which improves clinical efficacy with better safety profile.

One of the reason for Anti-Wrinkle cream showing better results could be due to use of various combination of ingredients for an extended spectrum of activity interfering with the different steps of photoaging. The association of various ingredients with different mechanisms of action appears to be a useful strategy to improve clinical efficacy, and the risk of adverse effects as in the present study.

Serious side effects:

Participants of this study were asked to evaluate the presence of adverse side effects of the herbal Anti wrinkle cream treatment. None of the patients exhibited any adverse effect to theAnti wrinkle cream.

Conclusion:

In our study it was noted that, Anti-Wrinkle cream appears to be effective and safer alternative with 6 weeks of therapy. In terms of efficacy, there was a moderate to significant reduction in the MFWS score for the treatment groups, brought about with 6 weeks of treatment.

The patient compliance was significantly good and was recommended by majority of the patient . The Anti wrinkle has also shown Anti aging effects viz. Improved Skin Tone and Colour ,Reduction of Dark spots and Circles in 40% patients .

Limitations of study and future recommendations:

This was only a pilot study conducted on 30 subjects and was done only at one centre with limited end points and shorter duration. Further more comprehensive and multi centric studies can be done with multiple parameters to evaluate the potential benefits of this product.

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