

AN OPEN LABELED, TWO ARMED, PROSPECTIVE RANDOMIZED CONTROLLED PHASE 2 CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF “HERBAL UNDER EYE CREAM” IN REDUCING EYE STRAIN .

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ABSTRACT :

In this modern era each and every body part is facing harmful effects. Eyes are also having such effects due to sedentary lifestyle. Ayurveda has mentioned few regimens to maintain the health of eyes such as *Tarpan* and *Anjan*. But this may not be possible in daily routine due to busy schedule. Hence an under eye cream is prepared for local application around eyes. Study was carried out in two groups. Group A :Experimental group consisting of 30 female individuals age between 15 to 45 years with complaints related to eye strain such as dark circles, wrinkles, and dryness of eyes. Group B:Control group consisting of 30 female individuals using already existing market product i.e. under eye gel. Herbal under eye cream contents –*Manjishtha, Sariva, Triphala-Amalaki, Haritaki, Bibhitaki, Lodhra and Chandan* all these were taken in churn form, cow ghee, Rose essence and water. It was prepared by method of *shatadhauta ghruta* preparation. 600gms of pure cow ghee was taken and was heated to melt. 20gms each of above mentioned five drugs were obtained from GMP certified company. These were mixed to make a total of 100gms powder. Water was added to this powder and 150 gms of *kalk* was prepared. This *kalk* was added to the melted ghee. This ghee was continued on flame till the *ghruta siddha lakshan* were observed. 480 gms of *Siddha ghruta* was obtained which was separated and allowed to cool in a plate. Cold water was added to this above the level of this obtained *Siddha ghruta*. When the water became slightly warm (due to continuous rubbing) it was replaced by fresh sample of cold water, in this way rubbing and washing process was repeated 100 times. At the end cream was obtained by discarding all the water. Rose essence was added. Cream was packed in plastic containers of 15gms each.

The cream was applied twice daily for 30 days. Follow up was taken after 15 days. A gentle massage for 2min was given after application. The results of both the groups were statistically compared by using chi-square test. Herbal under eye cream is effective in reducing the eye strain than already available under eye gel. The effects on dark circles, dryness and wrinkles was more appreciable in experimental group than control group. It is cheaper than under eye gel. The effects of under eye cream lasts longer. It does not have any adverse effect on health.



KEY WORDS: Eye strain, Herbal under eye cream, dark circles, dryness, wrinkles, soothing effect.

INTRODUCTION :

Changed life style and increasing pollution is having bad effects on our face as it is the most sensitive part of our body. The stress and strain of eyes is causing dark circles, under eyes,. The females using cosmetics daily are also facing this problem as a result of harmful effects of synthetic products. The people working with computers or the people involved in some minute works such as stitching are more prone to these dark circles under eyes.

In Ayurveda more emphasis is given for maintenance of health rather than curing a disease .The procedures such as *Tarpan* are suggested to get rid off under eye dry circles. Periorbital dark circles are a result of the thin layer of skin below your eyes showing the blood vessels and the blood they contain more clearly than anywhere else on your body. The skin around the eyelids, called peri orbital skin, is on average about 0.5 mm thick compared to an average of about 2 mm thick on most of the rest of your body. Dark bluish circles are (usually) just the result of light being reflected back off of the blood vessels sitting just below the surface of that incredibly thin patch of skin. This is the same reason facial bruises are more prominent below or around the eyes; the thin skin just shows the blood from the ruptured blood vessels a little bit more clearly. Many systemic diseases also show this symptom such as allergies, eczema, chronic diseases of any kind, anaemia etc. In this study an attempt is made to prepare

a cream on the basis of specific Ayurvedic formulation method without using any chemical compounds. The application of this is soothing and helps in improving the skin texture and colour there by reducing the dark circle. The massage of this cream can be done twice daily around the eyes to get relief from strain of eyes and improve health of eyes.

AIM :

To evaluate the efficacy of herbal under eye cream in maintaining healthy eyes.

OBJECTIVES :

Primary : a) To compare the efficacy of herbal under eye cream with that of existing market product.

Secondary : a)Determining the acceptance and tolerability of herbal under eye cream.

b)Evaluating safety and efficacy of herbal under eye cream in maintaining healthy eyes their by reducing under eye dark circles, wrinkles,and dryness of eye which is seen do to eye strain.

HYPOTHESIS :

Herbal under eye cream is effective in maintaining health of eyes there by reducing under eye dark circles, wrinkles, and dryness of eyes and proving soothing effect to eyes.

Study design:

Open labeled ,Two armed, prospective Randomized controlled phase 2 clinical study.

MATERIALS AND METHODOLOGY

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Study was carried out in two groups. Group A : Experimental group consisting of 30 female individuals age between 15 to 45 years with complaints related to eye strain such as dark circles, wrinkles, and dryness of eyes. Group B: Control group consisting of 30 female individuals using already existing market product i.e. under eye gel. The cream was applied twice daily for 30 days. follow up was taken after 15 days. A gentle massage for 2min was given after application. The results of both the groups were be statistically compared.

Herbal under eye cream:

Contents–

Manjishtha-Rubia cordifolia

Sariva –Hemidesmus indicus

Triphala-Amalaki-Emblica officinalis

Haritaki-Terminalia chebulla,

Bibhitaki–Terminalia bellerica

Lodhra-Symplocos Racemosa

Chandan-Santalum album all these were taken in churn form, cow ghee ,Rose essence and water. The cream was be prepared by a specific method of cream preparation in Ayurveda.

Method of cream preparation :

The method used to prepare cream is similar to the making of *Shatadhauta Ghruta*. 600gms of pure cow ghee was taken and was heated to melt. 20gms each of above mentioned five drugs were obtained from GMP certified company

.these were mixed to make a total of 100gms powder .water was added to this powder and 150 gms of *kalk* was prepared .This *kalk* was added to the melted ghee. This ghee was continued on flame till the *ghruta siddha lakshan* were observed. 480 gms of *siddha ghruta* was obtained which was separated and allowed to cool in a plate. Cold water was added to this above the level of this obtained *siddha ghruta* .When the water became slightly warm (due to continuous rubbing) it was replaced by fresh sample of cold water , in this way rubbing and washing process was repeated 100 times. At the end cream was obtained by discarding all the water .Rose essence was added. Cream was packed in plastic containers of 15gms each.

CRITERIA FOR SELECTION:**Inclusion-**

- 1.Age- 18-45yr
- 2.Sex- Female
- 3.Person from any economic class will be selected

Exclusion-

- 1.Person suffering from any systemic disease
- 2.Pregnant ladies

Parameters of study :

Objective : Fairness strip of skin colour to assess under eye dark circles.

Subjective :to assess wrinkles and dryness.

Gradation was be done as follows:

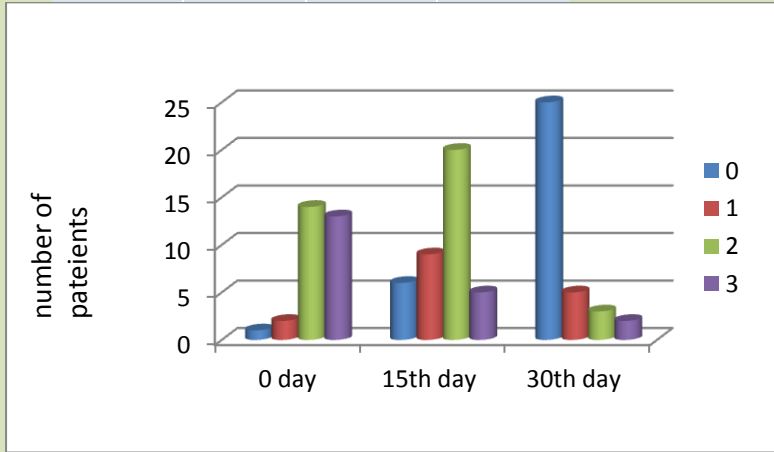
Grade 0-no symptoms, Grade 1-mild, Grade 2-moderate, Grade 3-severe.

OBSERVATIONS :

The effects of both the groups i.e. group A and Group B were compared on 30th day by using Chi-square test.

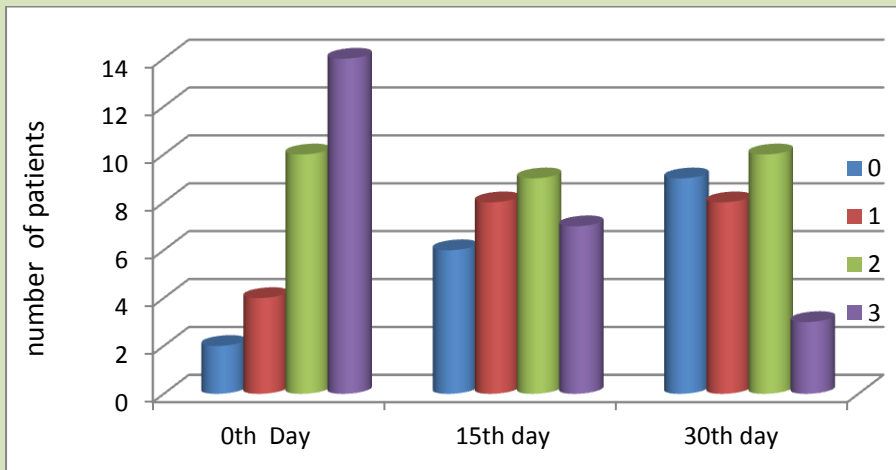
Assessment of Under Eye Dark circles: Group A

Grade	0 day	15th day	30th day
0	1	6	25
1	2	9	5
2	14	20	3
3	13	5	2
Total	30	30	30



Group B:

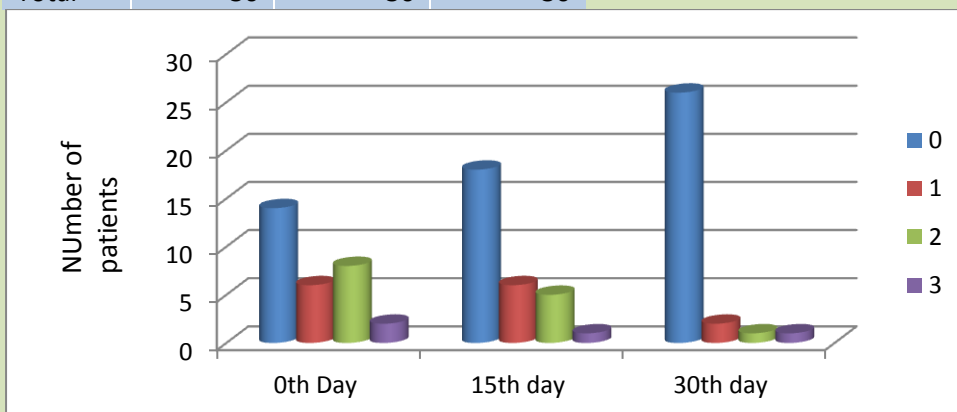
Grade	0th Day	15th day	30th day
0	2	6	9
1	4	8	8
2	10	9	10
3	14	7	3
Total	30	30	30



Chi square value :11.8766, $p < .05$ Hence herbal under eye cream is more effective in reducing the under eye dark circles.

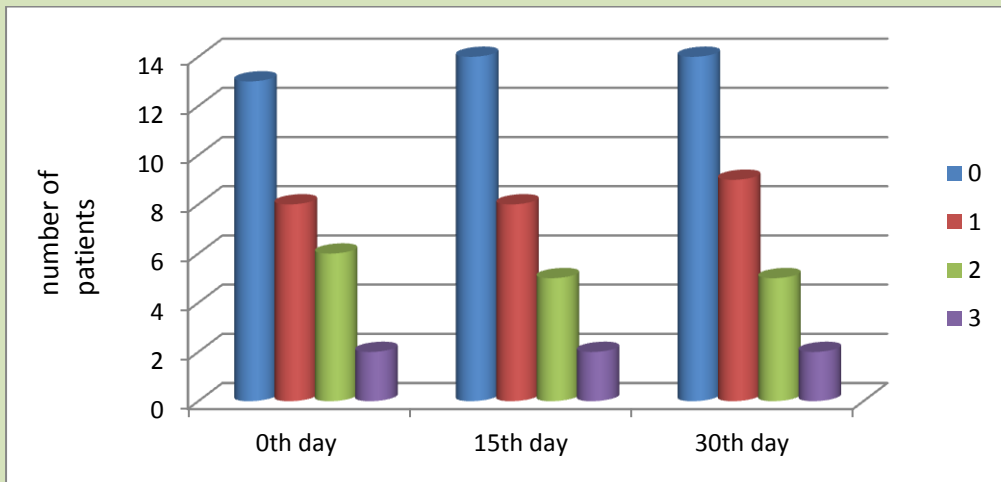
B)Wrinkles .Group A

Grade	0th Day	15th day	30th day
0	14	18	26
1	6	6	2
2	8	5	1
3	2	1	1
Total	30	30	30



Group B :

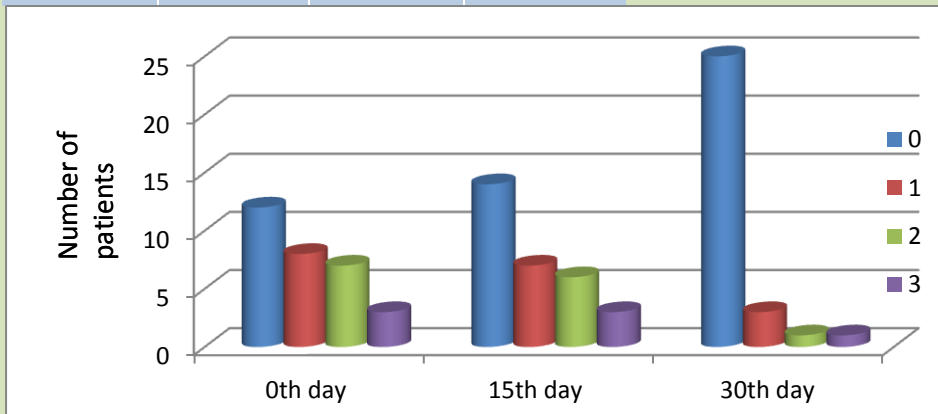
Grade	0th day	15th day	30th day
0	13	14	14
1	8	8	9
2	6	5	5
3	2	2	2
Total	30	30	30



Chi –square value :11.0545, p<.05Hence under eye cream is more effective in reducing under eye wrinkles.

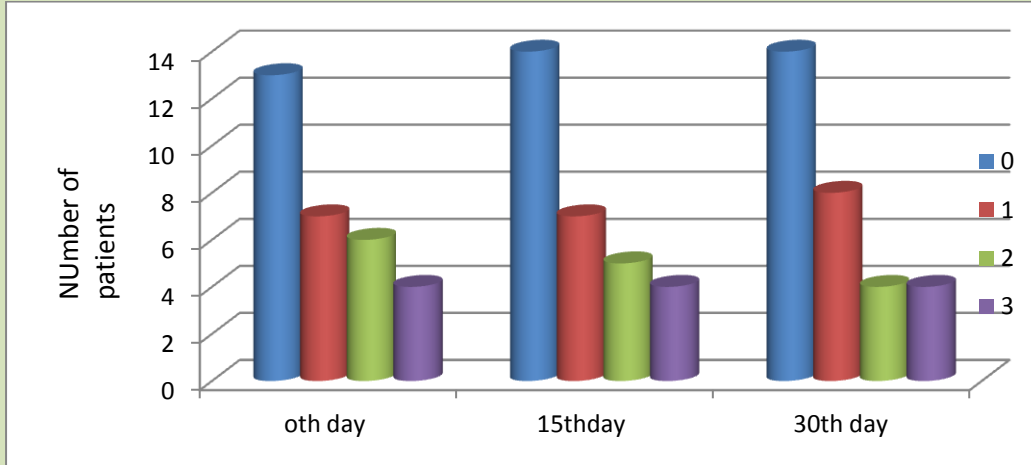
C)Dryness,Group A

Grade	0th day	15th day	30th day
0	12	14	25
1	8	7	3
2	7	6	1
3	3	3	1
Total	30	30	30



Group B :

Grade	oth day	15thday	30th day
0	13	14	14
1	7	7	8
2	6	5	4
3	4	4	4
Total	30	30	30



Chi-square value :8.9753, $p < 0.05$. Hence under eye cream is more effective in reducing dryness and this effects lasts longer as compared to under eye gel of Himalaya.

Utility of product :

- Effective and safe herbal cream to maintain healthy eyes there by reducing under eye dark circles, wrinkles and dryness.
- Good soothing agent to reduce eye strain.

Benefit to society :

- Herbal under eye cream without any side effects.
- The only cream without any synthetic product.

- Reduces the strain of eyes due to its soothing effect.

Cost effectiveness:

- Very economical .
- Approximate amount is Rs25. per 20gms .

CONCLUSION :

Herbal under eye cream is effective in reducing the eye strain than already available under eye gel . It is cheaper than under eye gel. The effects of under eye cream lasts longer. It does not have any adverse effect on health.

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