

Clinical and Efficacy studies of Pilarsh Gel in Piles: a Pilot PMS Study

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ABSTRACT

The objective of this study is to evaluate Clinical and Efficacy studies of Pilarsh Gel in Piles :A Pilot PMS Study. Sixty-two patients with symptomatic hemorrhoids were randomized to receive Pilarsh Gel or placebo Gel for the period of 3 weeks. The patients were evaluated comparing before and after treatment with respect to anal irritation, bleeding, anal itching, pain, defecation discomfort and swelling sense. Results were evaluated using overall subjective improvement (%).

Significant results were obtained after the treatment of 3 weeks with respect to anal irritation, bleeding, pain as well as swelling sense. Significant results was also seen comparing pre and post treatment of Pilarsh Gel. This Clinical study showed that, Pilarsh Gel helps in improving clinical signs and symptoms in patients with Piles.

I. INTRODUCTION:

Piles or Hemorrhoids is a condition involving swollen and inflamed veins in the rectum (internal) or anus (external). It requires proper treatments. Various symptoms related to Piles, includes bleeding, pain, itching, swelling or any palpable abnormality in the perianal region.

Various factors that aggravate includes Constipation, aging, pregnancy, obesity. Ayurveda offers holistic treatment which includes oral tablets and application of Gel or cream. Ancient texts describes use of many medicinal plants in the form of cream or gel for the treatment of Piles. It mentions the use of combination of plants which has anti-inflammatory effect as well as anti-infective effect. Many research papers have mentioned the use of ayurvedic cream in clinical use. Pilarsh Gel, is an ayurvedic gel which contains Neem, Nirgundi, Triphala, guggul, Karanj Oil, Daruharidra, Yashtimadhu, Karpoor and Sesame oil. All the plants have been reported to be useful in Piles. Pilarsh Gel have been used by doctors since many years and have been supported it for use in

Piles. Manily it has following effects as follows : 1. Exerts analgesic & anti-inflammatory actions, 2. Relieves pain and itching, 3. Arrests bleeding & checks infections, 4. Shrinks pile mass

II. METHODS:

Participants

A double-blind, randomized placebo-controlled clinical trial was conducted between June 2018 and December 2018 at an outpatient special clinic of Yash Clinic and research Center. A total of 62 patients with Piles were included in the study.

Inclusion Criteria: Not less than 18 years of age, clinically confirmed by doctor for mild to moderate piles included in the study.

Exclusion criteria: 4th-degree hemorrhoids; pregnancy; breast-feeding, previous history of anorectal surgery or non-conservative treatment; suffering from other diseases in addition to hemorrhoids, such as colorectal cancer, ulcerative colitis, Crohn's disease, anal fissure or inflammatory bowel diseases; and severe allergy to these plants.

Design of Study, Assessment parameters and End Point:

Eligible patients were selected after clinical examination by qualified doctor and base line parameters were recorded. Selected patients were then randomly segregated into two groups to receive either Pilarsh Gel (n = 31) or placebo (n = 31). Patients were made understand as how to apply the gel and placebo gel two times a day for the period of 3 weeks.

Statistical analysis

Data was processed using statistical model where significance value with $P < 0.05$

III. RESULTS:

62 patients with piles successfully completed the clinical trial. The average age of patients was (45 ± 10) years. The average age of patients in the treatment group was (43 ± 13) years also, the average age of the patients in the placebo group was (43 ± 9) years. There were no significant differences in the basic characteristics of the 2 groups.

As per the scoring pattern, patients were evaluated before and after treatment of 3 weeks. Following points were taken for consideration like anal irritation, bleeding, anal itching, pain, defecation discomfort and swelling sense with scoring from 0 – 5.

Based on the results, distribution of anal irritation, bleeding, anal itching, pain, defecation discomfort and swelling sense before and after the intervention in the treatment group were significantly different ($P < 0.05$) (Table No. 1, 2 and 3). There was significant difference found between treatment group and placebo group. There were no statistically significant differences before and after the intervention with respect to placebo group ($P > 0.05$) (Table No. 1, 2 and 3).

IV. DISCUSSION:

In our this clinical study patient with Pilarsh gel treatment showed significant beneficial effects as compared to placebo treatment.

The composition of Pilarsh gel includes key ingredients like Neem, Nirgundi, Triphala, guggul, Karanj oil, Yashtimadhu, Daruharidra and Karpoor. These herbs are extracted in water and Till Oil is used for snehpakk preparation. Then this oil is used for Gel Preparation. The observed beneficial effects can be explained by the previously described, anti-inflammatory, anti-oxidant, anti-constipation activity of Triphala, Neem, Nirgundi and Guggul. Sesameoil by inhibition the release of inflammatory mediators and reduction of NF- κ B activation can be beneficial for treatment of inflammatory diseases.

Jan et al 19 showed the anti-inflammatory activities of Sesaminoltriglucoside (STG), the main sesame lignan, in rats via metabolism of intestinal microflora and reduction of interleukin 6 and tumor necrosis factor-alpha. Also, there are clinical trials showing that the intake of sesame caused reduction of oxidative stress.²⁰ Clinical studies on the efficacy of Sesame oil have been mainly

performed on oxidative stress in patients with hypertensive, type 2 diabetes mellitus and dyslipidemia. The results showed that Sesame oil is characterized by increasing antioxidants and reducing oxidative stress markers.²¹⁻²⁴

Studies on compounds isolated from Guggul demonstrated its use in traditional medicine to treat inflammation. Neem showed to be having antibacterial as well as healing properties. Various studies show that Nirgundi is having powerful anti-inflammatory activity.

V. CONCLUSION:

Pilarsh Gel showed beneficial activity for the treatment of Piles and Hemorrhoids.

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Table 1: Comparison of the main symptoms before and after the intervention among patients in both groups

Variable	p Value	
	Pilarsh Gel	Placebo group
Anal irritation	0.002	0.18
Bleeding	0.012	0.25
Anal itching	<0.001	<0.001
Pain	<0.001	0.07

Defecation discomfort	<0.001	0.125
Swelling sense	0.001	0.508

Table 2:Symptoms score in Pilarsh Gel and placebo groups before treatment in the scores from 0 to 5

Parameter	Pilarsh Gel	Placebo Group	p Value
Anal irritation	5	5	0.496
Bleeding	4	4	0.265
Anal itching	5	5	0.310
Pain	5	5	0.100
Defecation discomfort	5	5	0.139
Swelling sense	4	3	0.208

Table 3: Symptoms score in Pilarsh Gel and placebo groups After treatment of 3 weeks in the scores from 0 to 5

Parameter	Pilarsh Gel	Placebo Group	p Value
Anal irritation	1	4	0.001
Bleeding	0	3	0.01
Anal itching	1	5	0.001
Pain	0	4	0.01
Defecation discomfort	1	4	0.001
Swelling sense	0	3	0.035