



**ORIGINAL RESEARCH PAPER**

**Unani Medicine**

**CLINICAL RESEARCH ON KALAWNJI (*NIGELLA SATIVA* LINN) IN PATIENTS WITH PCOS (POLYCYSTIC OVARIAN SYNDROME).**

**KEY WORDS:** *Kalawnji*, *Nigella Sativa* Linn, PCOS.

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**ABSTRACT**

**Background:** The prophet Muhammad (PBUH) reportedly recommended black cumin as a “cure-all” to his associates in Arabia 1400 years ago. It remains one of the most famous medicinal herbs in the Muslim world. It is included in the list of natural medicine of *Tibb-e Nabvi* (Prophetic medicine) and in Arabic it known as “*Habb-ul Barkah*” which means the seed of blessing. In Unani system of Medicine, *Kalawnji* (*Nigella Sativa* Linn) is regarded as a valuable medicine for a number of diseases. It is a small genus of annual herbs found in Southern Europe and Western Asia, but chiefly in the Mediterranean region.

**Objective:** To study the safety and efficacy of *Kalawnji* (*Nigella Sativa* Linn) in patients with PCOS.

**Methods:** The study was conducted in the Regional Research Institute of Unani Medicine, University of Kashmir, Srinagar, JK, from December 2018 to Aug 2019. In this study the patients were divided into two groups – test and control by randomization chart. There were some subjective and some objective parameters taken in the research. The follow up check-ups were done on 15<sup>th</sup>, 30<sup>th</sup>, 45<sup>th</sup>, and 60<sup>th</sup> day. Reinvestigations were done on 61<sup>st</sup> day.

**Results:** The data shows that *Kalawnji* (*Nigella Sativa* Linn) found effective in regulating the menstrual cycles, hirsutism, weight loss and B.M.I.

**Conclusion:** The *Kalawnji* (*Nigella Sativa* Linn) is safe and effective on standard dosage in relieving the symptoms and signs of PCOS.

**INTRODUCTION**

**Botanical name:** *Nigella Sativa* Linn<sup>1,2,3,4,5</sup>

**Family:** Ranunculaceae<sup>1,4,5</sup>

**Vernacular Names:**

**English:** Black cumin,<sup>3,4,5,6,7</sup> Small fennel,<sup>1,3,4</sup> Roman coriander,<sup>4</sup> Nutmeg flower<sup>7</sup>

**Arabic:** *Habbat-us- Soudah*,<sup>4,6,7,8,9</sup> *Habb-ul Barkah*,<sup>4,10</sup> Kaboodan<sup>2</sup> Kamune-asvad,<sup>7</sup> Kamoon Hindi.<sup>10</sup>

**Tibbi:** Kalawnji,<sup>1</sup> Kamazarius<sup>1</sup>

**Unani:** Melathion,<sup>4</sup> Snoo,<sup>2</sup> Sheenoo<sup>2</sup>

**Persian:** Sh-ouniz,<sup>4,6,7,8,10</sup> Siyahdanah,<sup>7,10</sup> Shownooz,<sup>2</sup> Siyahbiranj<sup>7</sup>

**Urdu:** Kalawnji<sup>4</sup>

**Hindi:** Kalonji,<sup>2,7,11</sup> Mugrela,<sup>2,6,7</sup> Kala-jira<sup>7</sup>

**Sanskrit:** Krishna-jiraka,<sup>4</sup> Kanchi<sup>8</sup>

**Marathi** Kali jeera<sup>4</sup>

**Sindhi:** Kaloodi<sup>9</sup>

**Plant Taxonomy**<sup>12</sup>

**Kingdom:** Plantae

**Clade:** Angiosperms

**Clade:** Eudicots

**Order:** Ranunculales

**Family:** Ranunculaceae

**Genus:** *Nigella*

**Species:** *N. Sativa*

**Mizaj (Temperament):**

*Harr* (Hot) 2<sup>nd</sup> 6,10 *Yabis* (Dry) 2<sup>nd</sup> 6,10

*Harr* (Hot) 3<sup>rd</sup> 2,8,11,13 *Yabis* (Dry) 3<sup>rd</sup> 2,8,11,13

**Parts used:** Dried fruit, Seeds and oil of seeds<sup>2,10</sup>

**Shelf life of seed:** 7 years<sup>10</sup>

**Dosage:** 4.5 gm<sup>13</sup> o.d.

**Afa'al (Actions)**

Unani Physicians have mentioned various actions of *Nigella Sativa* in classical texts. The action that is described in this paper is *Mudirr-e-Haidh* (emmenagogue). *Mudirr* is that kind of medicine which regulates menstrual cycles by making

blood *Lateef* and de obstruct the obstruction<sup>14,15,16</sup> i.e. they are *Mulattif Dam* (Demulcent) and *Mufattih Sudad* (de obstructant).

They act in 3 ways

1. Some medicines like *Abhal* (*Juniperus communis* Linn), *Kalawnji* (*Nigella Sativa* Linn) and *Parsiyooshan* (*Adiantum Capillus-vereris* Linn) stimulates the muscles of uterus leads to contraction and menstruation occurs.<sup>17,18</sup>
2. Some medicines like *Kuchla* (*Strychnos noxvomica* Linn) acts on nerves of uterus.<sup>17</sup>
3. Some medicines like *Sharrbat faulad*, *Khusta Faulad* and *Majoon Kabusul Hadeed* increases haemoglobin in blood, are used in those girls which have oligomenorrhoea, secondary amenorrhoea due to anaemia.<sup>17,19,20</sup>

**Methodology**

The clinical research on *Kalawnji* (*Nigella Sativa* Linn) in patients with PCOS (polycystic Ovarian Syndrome) was conducted in Regional Research Institute of Unani Medicine, University of Kashmir, Srinagar, JK. The study was conducted from December 2018 to August 2019. In this study female patients of reproductive age with PCOS, were enrolled after taking written inform consent. The patients were divided into two groups test group and control group by randomization chart by the computer generated method. The subjective parameters were irregular menstrual periods, unwanted hair growth on face & body and weight gain, whereas the objective parameters were PBAC-pictorial blood assessment chart and scoring system for assessment of menstrual blood loss, FGS- Ferriman and Gallwey score for hirsutism and BMI for weight gain. Group A patients were given test drug (*Safoof Kalawnji*) dosage 2.25g b.d with water, whereas, Group B were given tab metformin 500mg b.d with water for 60 days. The subjective and objective responses were assessed in four follow ups on 15<sup>th</sup>, 30<sup>th</sup>, 45<sup>th</sup>, 60<sup>th</sup> and reinvestigations were done on 61<sup>st</sup> day. The assessment of data was carried out based on the findings of pre and post treatment differences by means of PBAC, Ferrimans Gallwey score and BMI. The pre and post study data were subjected to statistical analysis. The observations were found clinically and statistically significant during the study.

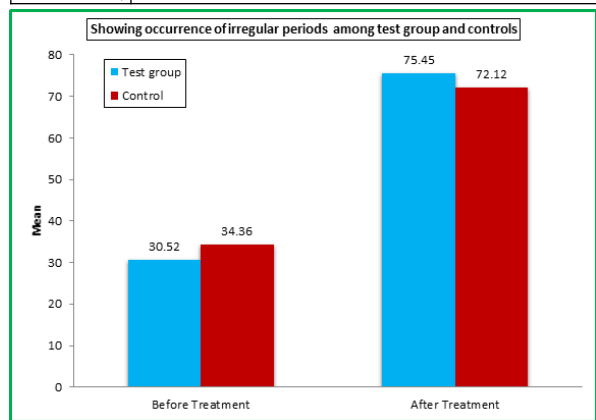
**OBSERVATIONS AND RESULTS**

The study findings are

**Distribution of patients according to occurrence of Irregular periods**

**Table 1: Showing occurrence of irregular periods among test group and controls**

| Irregular Periods                      | Before Treatment |       | After Treatment |       | Percentage of Improvement | P-value |
|--|------------------|-------|-----------------|-------|---------------------------|---------|
|  | Mean             | SD    | Mean            | SD    |                           |         |
| Test group                             | 30.52            | 13.76 | 75.45           | 14.11 | 147.21                    | <0.001* |
| Control                                | 34.36            | 19.69 | 72.12           | 15.16 | 108.43                    | <0.001* |
| <b>P-value (Test group vs Control)</b> | 0.3232           |       |                 |       |                           |         |

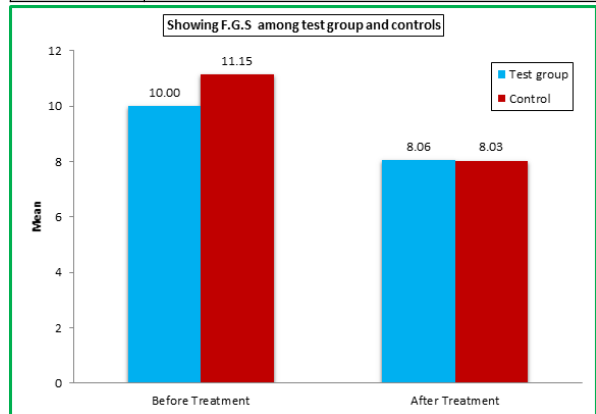


**Figure No. 1: Distribution of patients according to occurrence of Irregular periods**

**Distribution of patients according to Ferriman Gallwey score**

**Table 2: Showing F.G.S among test group and controls**

| F.G.S                                  | Before Treatment |      | After Treatment |      | Percentage of Improvement | P-value |
|--|------------------|------|-----------------|------|---------------------------|---------|
|  | Mean             | SD   | Mean            | SD   |                           |         |
| Test group                             | 10.00            | 2.95 | 8.06            | 1.43 | 19.40                     | <0.001* |
| Control                                | 11.15            | 2.22 | 8.03            | 1.01 | 27.98                     | <0.001* |
| <b>P-value (Test group vs Control)</b> | <0.001*          |      |                 |      |                           |         |



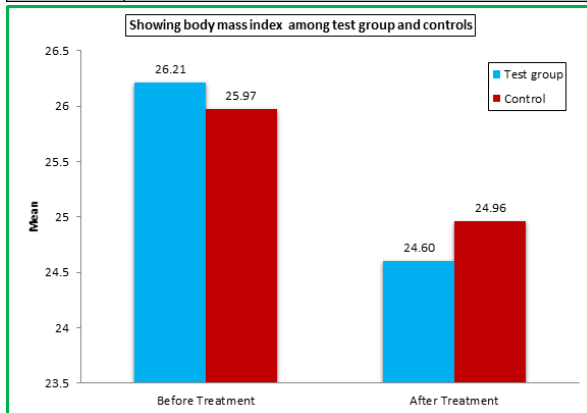
**Figure No. 2: Distribution of patients according to F.G.S**

**Distribution of patients according to Body mass index**

**Table 3: Showing body mass index among test group and controls**

| BMI        | Before Treatment |      | After Treatment |      | Percentage of Improvement | P-value |
|------------|------------------|------|-----------------|------|---------------------------|---------|
|            | Mean             | SD   | Mean            | SD   |                           |         |
| Test group | 26.21            | 3.92 | 24.60           | 3.77 | 6.14                      | <0.001* |

|  |        |      |       |      |      |         |
|--|--------|------|-------|------|------|---------|
| Control                                | 25.97  | 3.92 | 24.96 | 3.54 | 3.88 | <0.001* |
| <b>P-value (Test group vs Control)</b> | 0.0048 |      |       |      |      |         |



**Figure No. 3: Distribution of patients according to BMI**

**DISCUSSION**

The Clinical research on *Kalawnji (Nigella Sativa Linn)* in Patients with PCOS (Polycystic Ovarian Syndrome) was conducted on 66 patients with 33 in each group, treated for 60 days. The pre and post treatment effects as subjective and objective responses were assessed based on PBAC score, Ferriman Gallwey score and BMI.

Before treatment the mean of PBAC score was  $30.52 \pm 13.76$  in test group and  $34.36 \pm 19.69$  in control group. After treatment the mean was  $75.45 \pm 14.11$  in test group and  $72.12 \pm 15.16$  in control group. This data was found statistically significant in the both groups with p value  $< 0.001^*$  in test group and  $< 0.001^*$  in control group. (Table No. 1) The test drug was effective in relieving oligomenorrhoea and secondary amenorrhoea which may be due to the *Mudirr* (emmenagogue) property of the test drug. It is effective in inducing menstruation. This observation was based on PBAC and significant decrease in duration of cycle with  $p < 0.001^*$  which was extremely significant. Similarly in control group  $p < 0.001^*$  which was extremely significant. However on intergroup comparison the effect of test group when seen statistically was found insignificant in comparison to control.

Before treatment the mean of FG score was  $10.00 \pm 2.95$  in test group and  $11.15 \pm 2.22$  in control group. After treatment the mean of FG score was  $8.06 \pm 1.43$  in test group and  $8.00 \pm 1.00$  in control group. The data was found significant in both the groups with p value  $< 0.001^*$  in test group and  $< 0.001^*$  in control group. (Table 2) In the intergroup comparison the effect of test group when seen statistically was found highly significant in comparison to control at  $p < 0.001^*$ , suggesting that the test drug has better efficacy than the control drug. The test drug is emmenagogue and eliminates the cause of hirsutism. In classical text of Unani, hirsutism is mentioned as complication of amenorrhoea, so when amenorrhoea is treated, regulation of menstrual cycles occur and hirsutism disappeared. Similar finding was seen by Velazques E. with significant result on hirsutism with  $p < 0.001$  in comparison with metformin.<sup>21</sup>

Before treatment the mean value of BMI in  $\text{Kg/m}^2$  was  $26.21 \pm 3.92$  in test group and  $25.97 \pm 3.92$  in control group. After treatment the mean was  $24.60 \pm 3.77$  in test group and  $24.96 \pm 3.54$  in control group. This data was found statistically significant in both the groups at p values  $< 0.001^*$ . The effect of test group when seen statistically was found significant in comparison to control group with p value 0.0048. (Table 3) The reduction in BMI may be due to the anti-obesity property of *Kalawnji (Nigella sativa Linn)*.<sup>18,22</sup>

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Unani Medicine is the subject under which the paper should be included.

**CONCLUSION**

The data shows that test as well as control drug were found effective in regulating the menstrual cycles, hirsutism, and weight loss, with a single reported adverse effect in test group, while in control group, some girl's complaints of gastric irritation. It was also observed that the effect of test drug in some parameters like hirsutism, weight, BMI, was statistically very significant and encouraging in comparison with control drug. However in parameter like irregular periods control drug was encouraging in comparison with test drug.

However, long term study should be done on larger sample size for further exploration of the effects of test drug with modified methodology.

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