

# Clinical Trial to Find the (*Asbab*) Aetiology and (*Ilaj*) Treatment of (*Marz-e-Akyās Khusyat-ur-Rahim*) Polycystic Ovarian Syndrome (PCOS)

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## Abstract

**Introduction:** Polycystic Ovarian Syndrome (PCOS) is common endocrine disorder. It is clinically defined as the syndrome characterized by amenorrhoea, hirsutism and obesity associated with polycystic ovaries. Diagnosis is made on the Rotterdam criteria, established in 2003. The criteria require the presence of 2 of the following 3 criteria: 1. Oligo-ovulation or an ovulation. 2. Hyperandrogenism. 3. Polycystic ovaries through ultrasound evaluation. **Methods:** Diagnosed patients were enrolled in the trial into two groups: Test group (A) and Control group (B) after obtaining voluntary informed consent. The study was conducted at RRIUM, Naseem Bagh Campus, University of Kashmir from Dec 2018 to Aug 2019 after ethical approval. Total 89 patients were screened, 77 enrolled for the trial, 66 patients completed the study, 10 were drop out due to their personal reasons, 1 had adverse effect of menorrhagia after taking test medicine. The medicine is immediately stopped and patient recovers. The adverse effect of drug was sent to Pharmacovigilance unit. 66 diagnosed patients of PCOS were randomly divided into test group and control group, 33 patients in each group. Test drug (Safoof Kalawnji 2.25 g b.d with water) were given to group A and control drug Tab Metformin 500 mg b.d were given to group B for 2 months. Clinical assessment, biochemical tests and USG–pelvis were done for pre- and post-analysis. **Result:** The observations were clinically and statistically significant in both the groups. There are many aetiologies of PCOS, mentioned in our classical literature, one of the causes is ghalba bhalghm. There are many ways of alternative treatment, like *Ilaj bil ghiza* (Dietotherapy), *Ilaj bil dawa* (pharmacotherapy), *Ilaj bit-Tadbeer* (Regimenal Therapy). **Conclusion:** In this research, the pharmacotherapy was tested. The medicine used in this trial was powder of single herbal medicine, *Nigella sativa* Linn. This cause and effect of this clinical trial can be explained by *Ilaj bil Zid* and *Mudirr* properties of *Showneez* (*Nigella Sativa* Linn), mentioned by Zakariya Razi.

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## INTRODUCTION

The term poly is derived from Greek word “Polus” meaning numerous [1]. Cyst is derived from Greek word “Kystis” meaning *Tukhm daan* or *Baiza daan* [2]. Ovary is female gonad that produces ova [3–6]. Syndrome is derived from Greek word “Syndromos” meaning running together [7]. There is no universal accepted definition, but it has been recommended that PCOS requires the presence of two of the following three features [8].

- Menstrual irregularities.
- Clinical or biochemical androgen excess.
- Multiple cysts in the ovaries [8].

According to the available literature, the criteria to define polycystic ovary (PCO) are the presence of 12 or more follicles measuring 2–9 mm in diameter and increased ovarian volume ( $>10\text{ cm}^3$ ). The presence of a single polycystic ovary is sufficient to provide the diagnosis [9]. In Unani system of medicine, the disease has not been mentioned under the term of PCOS as the disease has been firstly described in 1935 as a syndrome of secondary oligomenorrhoea, sterility, and obesity associated with bilateral enlarged ovaries and anovulation. But in Unani classical literature, the description of the syndrome has been described vividly under the headings of *Qillat-i-tamth* (oligomenorrhoea), *Ihtibas al-tamth* (amenorrhoea), *Uqr* (sterility) [10–18]. The current definition of PCOS is almost same as defined by Unani physicians as shown in the following Table 1.

**Table 1.** Showing the similar statements of PCOS mentioned in Unani classical literature thousands of years ago.

| S.N. | Classical Text Definition                                                                                    | Current Definition                                                            |
|------|--------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| 1.   | <i>Qillat-i-tamth</i> / <i>Ihtibas al-tamth</i> for long period of time $> 2$ months [10–12, 14, 17].        | Oligomenorrhoea/Secondary amenorrhoea [8–9, 19–24].                           |
| 2.   | It occurs in fair and <i>Balghami</i> females [10–12, 14].                                                   | Many girls who develop PCOS are overweight [8–9, 19–24].                      |
| 3.   | Their body turns towards masculinity, beard appears and hair growth occurs on their body [10–12, 14, 17–18]. | Hyperandrogenism (Clinical and/or biochemical), i.e., hirsutism [8–9, 19–23]. |
| 4.   | Their voice's frequency becomes low, and their pitch becomes high, i.e., deepening of voice [10–12, 14, 17]. | Hoarseness of voice [8–9, 23].                                                |

## PREVALENCE

PCOS is the commonest endocrine disorder in women [9]. It occurs one in five women [4], the current incidence of PCOS is 5–6% is fast increasing lately due to change in the lifestyle and stress. It is also becoming a common problem among adolescents, developing soon after puberty [25]. It is prevalent in young reproductive age group (20–30%) [19]. PCOD is, nowadays, seen in young women who are overweight [25]. Many girls who develop PCOS are overweight in childhood and obesity is clearly a risk factor [21]. Even Indian National Family Survey (NFHS) indicates that at least 60% of married Kashmiri women report one PCOS or more reproductive health problems which are significantly higher in comparison to the All-India average of 40% [26].

## Causes (*Asbāb*)

- In modern system, the primary cause remains uncertain and is not known [8].
- In *Unani* medicine, the known cause is divided into two groups.
- *Causes inside the Rahim (Uterus)*: The main cause is in the uterus and they are:
  - *Sudda (obstruction)*: It may be caused by *Waram-al-Rahim* (Metritis) or by *Imtilā Dam* (Congestion) [10, 11].
  - *Ratq (imperforated hymen)*: It is also caused by *Ratq* (imperforated hymen), increase of meat in that area or by healing of an ulcer by which the inlet of capillaries is closed or narrowing of cervix or after abortion or due to trauma and after healing the inlet of capillaries gets closed [11, 12, 14].
  - *Ghalaba Balgham*: It may be due to accumulation of fat or due to *Ghalaba Balgham* which increases viscosity of blood leads to secondary amenorrhoea [11, 12].

Due to excessive fat, the capillaries of uterus become narrow, leads to *Ihtibās al-tamth* (amenorrhoea) [11, 12].

- *Causes outside the Rahim (Uterus)*: The uterus itself has no structural anomaly, but abnormality is due to nearby or surrounding organs or may be due to general features which are:
  - *Hummā* (pyrexia) [11, 12].
  - *Sū'-i-Mizāj Sādhij aur Māddī* (impaired temperament simple and compound) [11, 12].
  - *Istesqā* (Ascites) [11, 12].
  - *Sudda Jiger* (obstruction of liver) [11, 12].
- Obesity and cachexia causing obstruction (*Sudda*) [11, 12, 16].
- Power of digestion, strong enough to minimize the menstrual blood flow [11, 12].
- Weakness of liver [11–13].
- Excessive evacuation [11–12].
- Excessive exercise [11–12].
- Anaemia [27–28].
- *Barudat* and *Ratubat* leads to oligomenorrhoea, secondary amenorrhoea and sterility [29–30].

The other causes and risk factors as per literature are:

- *Involvement of Khilt: Khilt Balgham*, it is caused by *Ghaleez* (viscous) and *Barid Khilt* (cold humour), i.e., *Balgham* [10–12, 14–15, 17].
- *Season*: Winter and rainy season [10–11, 30].
- *Socio-economic status*: Upper class [25].
- *Mizāj (temperament): Bārid Ratab* [10, 15].
- *Built*: Obese, central obesity is recognised as an important contributing factor [8, 9, 19–24, 27, 30].
- *Complexion*: White [10, 14].
- *Stress*: During stress adrenal glands are stimulated to produce excess androgens [19, 25, 27, 28, 30].
- Change in lifestyle and diet [25].
- *Genetic predisposition*: PCOS is thought to have a dominant mode of inheritance as about 50% of first-degree relatives have PCOS [19, 25].
- *Malfunctioning of liver*: Unani Physician *Younus* has mentioned that secondary amenorrhoea occurs due to malfunctioning of liver [13, 27].

Moreover, it has been mentioned that menstruation in cold region occurs late and in hot region it occurs early [17]. The use of cold water makes disturbance in menstrual cycles [10, 30]. The females of Rome used to drink the ice water that is why their menstrual cycles were disturbed and *Tanqiya* does not occur properly [10]. It usually occurs in fair and those girls whose temperament is *Balghami* (Phlegmatic) [10–12, 14, 17]. The cold region has also some effect on menstrual cycles and leads to *Uqr* (sterility) [31].

## METHODOLOGY

The study design, an open randomized controlled clinical trial, has been carried out in the department of *Mo'ālajāt*, at Regional Research Institute of Unani Medicine, RRIUM, University of Kashmir, Srinagar. Before starting the trial, the protocol was submitted to Institutional Ethical Committee for ethical clearance. After ethical clearance the patients were selected from OPD of Regional Research Institute of Unani Medicine, RRIUM, Srinagar after taking case history, clinical examination with detailed history of the disease and necessary haematological, hormonal and radiological investigations. The demographic data, clinical symptoms, history, signs, follow up readings, before and after treatment investigation reports were recorded on the prescribed case record form (CRF) designed for the study. The clinical study was carried out by enrolling the diagnosed patients into two groups test and control by randomization chart by the computer-generated method. The clinical trial starts from December 2018–August 2019. A total 89 patients are screened, 77 fulfilled the inclusion criteria and enrolled in the trial, 10 were drop out, 1 had adverse reaction after taking test drug. 66 patients complete the trial,

33 patients in each group. The test group was administered *Safoof Kalawnji* 2.25 grams b.d with water for two months. The control drug metformin 500 mg b.d with water was given to control group for two months. The pre- and post-analysis were done by clinically, biochemically, and by USG. In case of USG, the result was statistically highly significant with p value < 0.001\* in test group and the data were statistically significant at p value 0.016 in control group. The finding validates the Zakariya Razi's statement mentioned in his book that *Showneez* (*Nigilla Sativa* Linn) is *Mudirr-i-hayd* (emmenagogue) and may be used in amenorrhoea caused by *Ghalaba Khilt Balgham* (phlegm) [10].

### Inclusion Criteria

- Patients were 14–43 years of females. The informed consent is obtained from the guardians in case of below 18 years.
- Menstrual disturbances oligomenorrhoea and secondary amenorrhoea.
- Central obesity – waist circumference > 88 cm.
- BMI < 35 kg/m<sup>2</sup>.
- Acne.
- Hirsutism.

### Exclusion Criteria

- Patients were below 14 and above 43 years of females.
- Males and transgender, because it is mentioned that menstruation does not occur in *Khasna* females.
- Pregnancy and Lactation.
- Systemic illness, such as liver, kidney, cardiac, pulmonary disease, hypertension.
- On oral contraceptives.
- Patients with hypermenorrhoea (menorrhagia), polymenorrhoea, (epimenorrhoea).
- Body Mass Index (BMI) > 35 kg/m<sup>2</sup>.

## OBSERVATIONS AND RESULTS

The observations and results based on Rotterdam's diagnosed criteria of PCOS is analyzed clinically and statistically. The observations were found clinically and statistically significant. The subjects were clinically assessed by:

- **PBAC:** Pictorial blood assessment chart and scoring system for assessment of menstrual blood loss, during period count the number of sanitary pads and/or tampons use each day (24-hour period). Calculate a score for each day, then add up the score at the end of the month. PBAC score used to assess the amount of bleeding is as follows (Tables 2 and 3) [32]:

**Table 2.** PBAC scoring system [32].

| Points    | Pads                                           |
|-----------|------------------------------------------------|
| 1 point   | For each lightly stained pad.                  |
| 5 points  | For each moderately stained pad.               |
| 20 points | For each completely saturated pad.             |
| Points    | Tampons                                        |
| 1 point   | For each lightly stained tampon.               |
| 5 Points  | For each moderately stained tampon.            |
| 20 points | For each completely saturated tampon.          |
| Points    | Clots/Flooding                                 |
| 1 point   | For each small clot (Australian 5 cent coin).  |
| 5 points  | For each Large Clot (Australian 50 cent coin). |
| 5 points  | For each episode of flooding.                  |

Before treatment, the mean of PBAC score (pictorial blood assessment chart) of test group was 30.52 ± 13.76 and control group was 34.36 ± 19.69 (oligomenorrhoea). After treatment, there was significant improvement clinically with the mean of PBAC score in test group was 75.45 ± 14.11 and control group was 72.12 ± 15.16. The p value is <0.001 in both the groups that is statistically significant.

**Table 3.** PBAC score used to assess the amount of bleeding is as follows [33].

| PBAC Score | Inference                        |
|------------|----------------------------------|
| 1–10       | Spotting.                        |
| 11–35      | Hypo menorrhea/ oligomenorrhoea. |
| 36–80      | Normal.                          |
| >100       | Menorrhagia.                     |

### HIRSUTISM SCORING SCALE OF FERRIMAN AND GALLWEY

Hirsutism, which is defined as androgen depended excessive male-pattern hair growth, affects approximately 10% of women. It is most often idiopathic, or the consequence of androgen excess associated with the polycystic ovarian syndrome (PCOS). Hair can be categorized as either *vellus* (fine, soft and non-pigmented) or terminal (long, course and pigmented). The number of hair follicles does not change over an individual's lifetime, but the follicle size and type of hair can change in response to numerous factors, particularly androgens. Hirsutism can be graded and given a "Ferriman–Gallwey score" by assessing the amount of hair in different parts of body [34]. The nine body areas that have androgen-sensitive areas are graded from 0 (no terminal hair) to 4 (frankly virile) to obtain a total score. A normal hirsutism score is <8. Greater than 8 to 36 shows degree of hirsutism. It is used to monitor the progress of hirsutism, or its response to treatment (Table 4) [9, 24].

**Table 4.** Hirsutism scoring scale of Ferriman and Gallwey.

| S.N. | Androgen Sensitive Area | Score | Score | Score | Score |
|------|-------------------------|-------|-------|-------|-------|
| 1.   | Upper lip               | 1     | 2     | 3     | 4     |
| 2.   | Chin                    | 1     | 2     | 3     | 4     |
| 3.   | Chest                   | 1     | 2     | 3     | 4     |
| 4.   | Abdomen                 | 1     | 2     | 3     | 4     |
| 5.   | Pelvis                  | 1     | 2     | 3     | 4     |
| 6.   | Upper Arms              | 1     | 2     | 3     | 4     |
| 7.   | Thighs                  | 1     | 2     | 3     | 4     |
| 8.   | Upper back              | 1     | 2     | 3     | 4     |
| 9.   | Lower Back              | 1     | 2     | 3     | 4     |

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  $8.06 \pm 1.43$  and in test group and  $8.00 \pm 1.00$  in control group. The data were found statistically significant in both the groups, since the p value was < 0.001\*. The intergroup comparison shows significant result with p value < 0.001\*.

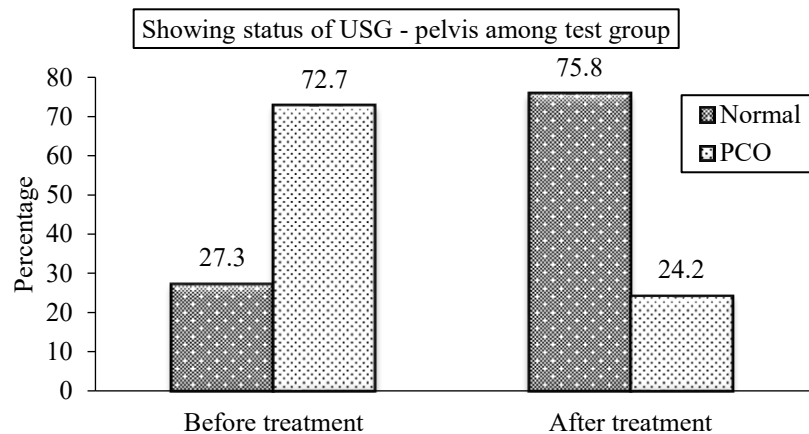
### ULTRASONOGRAPHY

The USG–pelvis was done in both the groups before and after the treatment to visualize the actual effect on polycystic ovaries. Before treatment the USG–pelvis was normal in 9 patients in test group. After taking *Safoof kalawnji* 2.25 g b.d with water for two months, the USG was repeated to see the result. It was found that 25 patients had normal USG. There was a significant reduction in ovarian volume. The data were found statistically significant with p value < 0.001\* (Table 5 and Figure 1).

**Table 5.** Distribution of patients according to USG–pelvis findings among test group.

| Showing Status of USG–Pelvis Among Test Group |                  |       |                 |       | P-Value |
|-----------------------------------------------|------------------|-------|-----------------|-------|---------|
| USG                                           | Before Treatment |       | After Treatment |       | <0.001* |
|                                               | No.              | %     | No.             | %     |         |
| Normal                                        | 9                | 27.3  | 25              | 75.8  |         |
| PCO                                           | 24               | 72.7  | 8               | 24.2  |         |
| Total                                         | 33               | 100.0 | 33              | 100.0 |         |

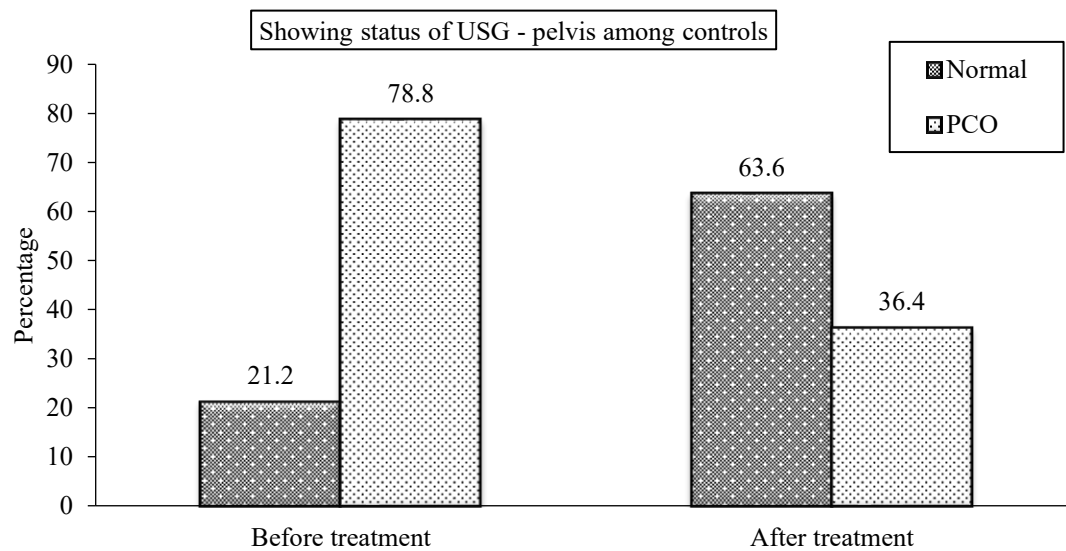
Note: Test Applied: McNemar's Test.



**Figure 1.** Distribution of patients according to USG – pelvis (test).

Before treatment out of 33 patients, USG findings of 9 (27.3%) patients were normal while the USG findings of 24 (72.7%) revealed PCO and after treatment 8 (24.2%) revealed PCO and 25 (75.8%) patients revealed normal ovaries on ultrasound.

Similarly, in control group the USG–pelvis was done before and after the treatment. Before treatment the USG– pelvis was normal in 7 patients in control group. After taking Tab Metformin 500 mg b.d with water for two months, the USG was repeated to see the result. It was found that 21 patients had normal USG. The data was found statistically significant with p value 0.016 (Table 6 and Figure 2).



**Figure 2.** Distribution of patients according to USG – pelvis (control).

**Table 6.** Distribution of patients according to USG–pelvis findings among controls.

| Showing Status of USG–Pelvis Among Controls |                  |       |                 |       | P-Value |
|---------------------------------------------|------------------|-------|-----------------|-------|---------|
| USG                                         | Before Treatment |       | After Treatment |       | 0.016   |
|                                             | No               | %age  | No              | %age  |         |
| Normal                                      | 7                | 21.2  | 21              | 63.6  |         |
| PCO                                         | 26               | 78.8  | 12              | 36.4  |         |
| Total                                       | 33               | 100.0 | 33              | 100.0 |         |

Note: Test Applied: McNemar's Test.

Before treatment out of 33 patients, USG findings of 7 (21.2%) patients were normal while the USG findings of 26 (78.8%) revealed PCO and after treatment 12 (36.4%) revealed PCO and 21 (63.6%) patients revealed normal ovaries on ultrasound.

## DISCUSSION

In test group, before treatment out of 33 patients, 9 (27.3%) revealed normal USG findings and 24 (72.7%) patients revealed Polycystic ovaries and after treatment 8 (24.2%) patients revealed Polycystic ovaries and 25 (75.8%) patients revealed normal ovaries. This data was found statistically highly significant with p value < 0.001\* (Table 5). In control group, before treatment out of 33 patients, 7 (21.2%) revealed normal ovaries and 26 (78.8%) revealed Polycystic ovaries and after treatment 12 (36.4%) patients revealed Polycystic ovaries and 21 (63.6%) revealed normal ovaries. This data was found statistically significant at p value 0.016 (Table 6). The finding was very close to the study done by Najem F that 74% of patients had USG features of polycystic ovaries [35]. The test drug was found more effective in inducing menstruation and resolving the ovarian cyst due to its *Mudirr* (emmenagogue), *Mulatif* properties and *ilaj bil zidd*, that means the *Mizaj* (temperament) of medicine is *Haar* (hot) and the temperament of disease is *Barid* (cold). The all USG's done before and after the treatment were submit to the department of *Moalajat*, *RRUM*, University of Kashmir, Srinagar.

## CONCLUSIONS

The one of the causes of PCOS may be *Ghalaba Balgham* (phlegm) according to involvement of *khilth*, and it can be treated by *Showneez* (*Nigella Sativa* Linn) as mentioned by *Zakariya Razi*. Vol. 9. This study validates his statement.

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