IVYSPRING INTERNATIONAL PUBLISHER

International Journal of Medical Sciences

2015; 12(10): 825-831. doi: 10.7150/ijms.13024

Research Paper

Efficacy of a Novel Fenugreek Seed Extract (*Trigonella foenum-graecum*, Furocyst™) in Polycystic Ovary Syndrome (PCOS)

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Received: 2015.06.23; Accepted: 2015.09.02; Published: 2015.10.03

Abstract

Polycystic ovary syndrome (PCOS) is one of the most prevalent hormonal disorders among women of reproductive age causing irregular menstrual cycles, excessive body or facial hair, miscarriage and infertility. The latter being a most common PCOS symptoms. Because the symptoms are seemingly unrelated to one another, PCOS is often overlooked and undiagnosed. The present study is an open label, one-arm, non-randomized, post-marketing surveillance study in 50 premenopausal women (18-45 years, BMI<42) diagnosed with PCOS using a novel *Trigonella foenum-graecum* seed extract (fenugreek seed extract, Furocyst, 2 capsules of 500 mg each/day) extract, enriched in approximately 40% furostanolic saponins, over a period of 90 consecutive days. The study was conducted to determine its efficacy on the reduction of ovarian volume and the number of ovarian cysts. Ethical committee approval was obtained for this study. Furocyst treatment caused significant reduction in ovary volume. Approximately 46% of study population showed reduction in cyst size, while 36% of subjects showed complete dissolution of cyst. It is important to mention that 71% of subjects reported the return of regular menstrual cycle on completion of the treatment and 12% of subjects subsequently became pregnant. Overall, 94% of patients benefitted from the regimen. Significant increases in luteinizing hormone (LH) and follicular stimulating hormone (FSH) levels were observed compared to the baseline values. Extensive blood chemistry, hematological and biochemical assays demonstrated the broad-spectrum safety. Furocyst caused significant decrease in both ovarian volume and the number of ovarian cysts. Serum ALT, BUN and CK were assessed to demonstrate the broad-spectrum safety of Furocyst. No significant adverse effects were observed. In summary, Furocyst was efficacious in ameliorating the symptoms of PCOS.

Key words: Fenugreek seed extract (Furocyst); polycystic ovary syndrome (PCOS); female subjects; cyst size; luteinizing (LH) and follicular stimulating hormone (FSH); safety

Introduction

Polycystic ovary syndrome (PCOS) is a major hyper-androgenic disorder in which a woman's hormones are out of balance (1,2). The disorder is associated with excessive body and facial hair, male-pattern baldness, acne, weight gain, high levels of androgens, pelvic pain, irregular or absence of periods, ability to have children, miscarriage and infertility, high anxiety levels, depression, as well as poor overall physical

appearances (1-4). Approximately 5 million women are affected with PCOS in the United States alone (1), and it can occur in girls as early as 11 years old (5). Untreated, it often precedes serious health problems, such as diabetes, heart disease, sleep apnea, and several other complications (1,4). Women with PCOS grow many small cysts on their ovaries leading to the term "PCOS". It is believed that the cysts lead to hormone imbalances and initiates all the complications in women (1,2,3,5).

The etiology behind PCOS is unclear, however, genetics may play a major role (3). It has been theorized that women with PCOS may have inherited it (3). As mentioned above, a major problem is hormonal imbalance, in which the ovaries make more androgens than normal. High levels of androgens in women affect the development and release of eggs during ovulation (3,4). Women with PCOS also produce too much insulin and excess insulin appears to enhance the androgen level (1-4).

Several therapeutic agents including metformin, cabergoline, myo-inositol, D-chiro-inositol, combined oral contraceptives and aromatase inhibitors have been recommended for therapeutic interventions of PCOS (6-10). De Leo et al. reported that natural estradiol and non-androgenic progesterone could be recommended as an oral contraceptive in women with PCOS who are insulin resistant and/or overweight (11).

However, selected studies demonstrate that phytopharmaceuticals are less invasive, less expensive and equally effective in the management of PCOS. Sandeep et al. (11) used RIKILT Yeast Androgen Bioassay (RAA) and demonstrated the anti-androgenic activities of *Nardostachys jatamansi* DC and *Tribulus terrestris* L. The researchers demonstrated the efficacy of the plants against PCOS induced by estradiol valerate in rats (11). Dietary fiber, flax seed, fish oil, chromium picolinate, *Urtica diocia*, *Serenoa repens* (saw palmetto), *Vitex agnus-castus* and *Foeniculum vulgare* seed (fennel seeds) demonstrated significant efficacy against PCOS (12-14). Marshall et al. (15,16) pointed out that PCOS may have a vital link with insulin resistance; and, therefore, the PCOS patients should be treated for insulin resistance (15,16). In another study, De Leo et al. (11) showed that estradiol and non-androgenic progesterone could be recommended as an oral contraceptives in women with PCOS who are insulin resistant and/or overweight (11). These findings clearly demonstrate the intricate association of insulin resistance and PCOS.

Previous studies in our laboratories revealed the novel anti-diabetic efficacy of fenugreek (*Trigonella foenum-graecum*) seed extract in animal model (17), which inspired us to carry out the present human clinical.

In the present investigation, we assessed the efficacy of a novel, patent-pending fenugreek (*Trigonella foenum-graecum*) seed extract enriched in furostanolic saponins (Furocyst), to determine its efficacy in an open label, one arm, non-randomized, post-marketing surveillance study in 50 premenopausal women (age = 18-45 years, BMI = 23.88 ± 4.72 kg/m^2, diagnosed with PCOS). The study was conducted over a period of 3 consecutive months. Clinical assessment was conducted to assess the reduction of ovarian volume, number of ovarian cysts and other related parameters.

Materials and Methods

Novel Trigonella foenum-graecum Seed Extract (Furocyst)

A patent-pending *Trigonella foenum-graecum* seed extract (Furocyst, Cepham Inc., Piscataway, NJ) enriched in approximately 40% furostanolic saponins was used in this study. A patent-pending water-ethanol extraction process was used to manufacture Furocyst in a GMP-NSF certified manufacturing plant.

Assay Kits and Equipment

Assay kits for plasma glucose, serum glutamic oxaloacetic transaminase (SGOT), glutamic pyruvic-transaminase (SGPT), alkaline phosphatase (ALP), blood urea nitrogen (BUN), creatinine, triglyceride (TG), high density lipoproteins (HDL), luteinizing hormone (LH) and follicular stimulating hormone (FSH) levels were purchased from Siemens USA (Authorized representative Schenker India Pvt Ltd, Gurgaon, Haryana, India). Hemoglobin levels (Hb) and total leukocyte count (TLC) were assessed using electronic impedance in a Beckman Coulter Counter (Beckman Coulter India Pvt Ltd, New Delhi, India). Ultrasound was conducted in a GE LOGIQ P5 ultrasound system provided by Wipro GE Healthcare Pvt Ltd (Bangalore, India).

Study Design

This multi-centric, open-label, single arm, non-randomized, clinical study (Protocol #CR001/PCOS-05-13) was approved by Institutional Review Board (IRB) and Institute Ethics Committee (Approval #CEC/2013/07/28/I dated July 28, 2013), was conducted in Garg Hospital (Gorakhpur, Uttar Pradesh, India) and in Hormone and Maternity Clinic (Meerut, Uttar Pradesh, India). The study was performed in compliance and accordance with ICH Guidelines for Good Clinical Practices (GCP), including the archiving of essential documents, and per international ethical standards guaranteed by the Declaration of Helsinki and its subsequent amend-

ments. All subjects provided duly signed consent forms with sufficient information to make an informed decision about their participation in this study. This consent form was submitted with the protocol for review and approved by the Institute Ethics Committee (IEC). The formal consent of a subject, using the IEC-approved consent form, was obtained before the subject submitted to any study procedure. The consent form was signed by the subject or legally accepted representative. Patient confidentiality was strictly maintained.

Subject Recruitment and Inclusion and Exclusion Criteria: The subjects were screened for the clinical study on the basis of the inclusion/exclusion criteria (Table 1). A total of sixty-seven subjects were screened and fifty subjects met the inclusion and exclusion criteria. No instructions were issued to enrolled subjects to change their routine physical activity schedules. The allocation of Furocyst was given after screening and enrollment. Furocyst (2 capsules of 500 mg each/day, Batch #FCYS0813) was consumed by subjects over a period of 3 consecutive months to determine efficacy reducing ovarian volume and the number of ovarian cysts.

Study Compliance: Allocation of Furocyst was accomplished by site staffs. Distribution of the investigational product were maintained in the IP accountability log provided by the sponsor. Each entry was maintained separately with the date/signature of the principal investigator and study coordinator.

The person responsible for the distribution of the product had also signed the IP accountability log. The accountability log was readily available at the time of audit.

Assessment of Safety: Plasma glucose, serum triglyceride and serum HDL cholesterol levels were assessed at the baseline and at the end of 90 days of treatment. Further, serum glutamic oxaloacetic transaminase activity (SGOT), serum glutamic-pyruvic transaminase activity (SGPT), serum alkaline phosphatase activity (ALP), blood urea nitrogen (BUN) and serum creatinine levels were meticulously checked at the baseline and at the end of 90 days of treatment to demonstrate the broad-spectrum safety of Furocyst. Finally, effect of Furocyst on hemoglobin level and total leukocyte count were assessed at the beginning and completion of the study.

Assessments of Efficacy: Laboratory investigations including biochemical and hematological parameters at baseline, completion of 1 month, completion of 2 months and end of study (at the completion of 3 months) were carried out as indicated in Table 3.

Ovarian volume, reduction in ovarian volume (both left and right) and effect on ovarian cysts were assessed using sonographic scan (18). Efficacy on menstrual cycle following completion of Furocyst treatment as compared to baseline was noted. Efficacy of Furocyst on luteinizing hormone (LH), follicular stimulating hormone (FSH) and LH/FSH ratio was assessed. Waist circumference and hematogram were also performed.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria
1. Premenopausal women between 18-45 years of age
2. BMI less than 42
3. Adequate hepatic, renal and hematological functions
4. Patients willing to give informed consent
Exclusion Criteria
1. Post-menopausal women
2. Women with hysterectomy
3. Patients with congenital adrenal hyperplasia
4. Patients diagnosed with Cushing's syndrome.
5. Patients diagnosed with androgen secreting tumors.
6. Patients with thyroid dysfunction (T3, T4 level is higher than that in normal women of reproductive age).
7. Patients with hypo-gonadotropic and hypo-gonadism (central origin of ovarian dysfunction).
8. Pregnant or lactating mothers.

Table 2. Demographic and Baseline Characteristics of the Subjects

Data	Age (Years)	Height (cm)	Weight (kg)	Waist Size (cm)	BMI	SBP (mm Hg)	DBP (mm Hg)	Pulse (per minute)
Mean	24.06	157.01	58.98	54.42	23.88	116.78	75.32	76.49
Median	23.00	157.50	60.00	49.50	22.50	116.50	70.00	76.00
Standard Deviation	5.35	5.22	12.27	21.28	4.72	12.14	8.74	4.74
Minimum	18	144.0	38	28	16.00	70	68	70
Maximum	39	168.0	96	90	40.00	134	110	87

Table 3. Assessment of Efficacy

Time Intervals	Clinical Examinations
At Baseline	Sonographic scan Luteinizing hormone (LH, IU/L) Follicle stimulating hormone (FSH, IU/L) LH/FSH ratio Waist circumference Triglycerides level High-density lipoprotein cholesterol (HDL) Fasting Glucose Liver function (SGOT, SGPT, ALP), Renal function (BUN and Creatinine) Heart function (Creatinine) Hematogram
Every Month (1 and 2)	Sonographic scan LH (IU/L) FSH (IU/L) LH/FSH ratio Waist circumference
End of Study (3rd Month)	Sonographic scan LH (IU/L) FSH (IU/L) LH/FSH ratio Waist circumference Triglycerides level HDL Fasting Glucose Liver function test (AST, ALT, ALP), Renal function test (urea and Creatinine) Hematogram

Adverse Events: Subjects were advised to record adverse events (if any) during the duration of the study. At each visit, the subjects were asked if they have experienced any uncomfortable problems or difficulties. Thus, adverse event reporting was strictly enforced.

Statistical Analysis

Data is expressed as mean ± SD. The baseline characteristics were compared with the outcome following completion of the dosing period. All parametric and non-parametric assessments were conducted.

Results

Effects on Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH)

Table 4 demonstrates the time-dependent effects of Furocyst on LH and FSH over the period of 3 months. A significant increase in LH was observed on completion of the Furocyst treatment as compared to baseline (p = 0.045*). Significant increases in FSH were observed at the completion of 2 months (p = 0.010*), and following completion of 3 months (p = 0.000**).

Table 5 demonstrates time-dependent decreases in LH/FSH ratio, but the changes are not significant.

Table 4: Effects on Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH)

Parameters	Mean ± SD (IU/L)	Statistical Analyses
LH Baseline	10.33 ± 7.25	-
LH 1 Month	8.98 ± 4.93	t-value 1.189, p = 0.241
LH 2 Months	10.64 ± 7.72	t-value 0.223, p = 0.825
LH 3 Months	13.93 ± 10.14	t-value 2.069, p = 0.045*
FSH Baseline	5.36 ± 1.73	-
FSH 1 Month	5.49 ± 1.82	t-value 0.473, p = 0.638
FSH 2 Months	6.38 ± 2.37	t-value 2.685, p = 0.010*
FSH 3 Months	8.36 ± 3.34	t-value 5.767, p = 0.000**

Data are expressed as mean ±S.D. *, ** = Significant reduction

Table 5: Effect on Luteinizing Hormone (LH)/Follicle Stimulating Hormone (FSH) Ratio

LH/FSH Ratio	Mean ± SD	Statistical Analyses
Baseline	3.16 ± 7.98	-
1 Month	1.67 ± 1.00	t-value 1.211, p = 0.232
2 Months	1.56 ± 0.92	t-value 1.300, p = 0.200
3 Months	1.61 ± 0.81	t-value 1.189, p = 0.204

Data are expressed as mean ± S.D.

Changes in Ovary Volume

At the end of the study, significant reductions in both left and right ovary volumes (cm^3) were observed following treatment with Furocyst. Left ovary volume was reduced by 17.82% (p = 0.101), while right ovary volume was reduced by 28.25% (p = 000**) (Table 6).

Table 6. Changes in Ovary Volume

Data	Left Ovary Volume (cm^3)		Right Ovary Volume (cm^3)	
	Baseline	Completion of Treatment	Baseline	Completion of Treatment
Mean ± SD	12.23 ± 5.13	10.05 ± 4.19	14.00 ± 6.27	10.00 ± 4.19
Decrease (%)	17.82		28.57	
Statistical Analyses	t-value 2.013, p = 0.101		t-value 4.443, p = 0.000**	

Data are expressed as mean ± S.D. **Significant reduction

Effect on Cyst

A total of 47 subjects demonstrated reduced cyst size. Of these, 36 subjects exhibited no cyst at the completion of the study and 6 subjects got pregnant during the study. Overall, 94% subjects responded to Furocyst treatment (Table 7).

Table 7. Overall Response Following Completion of Treatment

Subjects	Number of Subjects	Percentage (%)	Percentage of Patients Responded to Treatment (%)
Pregnant Subjects	6	12	94
Patients with Complete Dissolution of Cyst	18	36	
Reduced Cyst Size	23	46	
No Response	3	6	
Total Patients	50	100	

Effect on Menstrual Cycle and Pregnancy

During enrolment, 81% patients had prolonged menstrual cycle, 10% patients had irregular cycle, and approximately 10% patients had primary infertilities. Significant improvement in menstrual cycle was observed following Furocyst supplementation. Following completion of the last visit, 71% of subjects had regular cycles, 19% of subjects reported prolonged cycle and approximately 10% of subjects reported primary infertility. None of the patients reported irregular cycle at the end of the treatment schedule (Table 8).

Table 8. Effect on Menstrual Cycle

Menstrual Cycle	Visits				
	Baseline (%)	1 Month (1%)	2 Months (%)	3 Months (%)	Total (%)
Irregular Cycles	2 (95.2%)	2 (95.2%)	1 (4.76%)	0 (0.00%)	5 (5.95%)
Primary Infertilities	2 (95.2%)	2 (95.2%)	2 (95.2%)	2 (95.2%)	8 (95.2%)
Prolonged Cycles	17 (80.95%)	17 (80.95%)	11 (52.38%)	4 (19.05%)	49 (58.33%)
Regular Cycles	0 (0.00%)	0 (0.00%)	7 (33.33%)	15 (71.43%)	22 (26.19%)
Total	21 (100%)	21 (100%)	21 (100%)	21 (100%)	84 (100%)

During the treatment, a significant percentage (%) of population got pregnant during the treatment. It was observed that 12% of study population got pregnant after the treatment. Three pregnancies were observed after 30 days, one each after 39-, 70- and 84 days of treatment.

Effects on Hemoglobin Levels (Hb) and Total Leukocyte Count (TLC)

A significant increase in Hb levels was observed on completion of the Furocyst treatment as compared to the baseline (p = 0.000) (Table 9). No significant change was observed in the TLC. No significant change in hemogram was observed.

Table 9. Hemoglobin Level (Hb) and Total Leukocyte Count (TLC)

Data	Hemoglobin Levels (Hb)		Total Leukocyte Count (TLC)	
At Baseline	12.37 ± 1.047	t-value = 5.442	7.37 ± 2.43	t-value =
On Completion (End of 3 months)	13.00 ± 0.926	p = 0.000**	8.77 ± 7.90	1.123 p = 0.268

Data are expressed as mean ± S.D. **Significant change

Effects on Serum Glutamic Oxaloacetic Transaminase (SGOT), Glutamic Pyruvic-Transaminase (SGPT), Alkaline Phosphatase (ALP), Blood Urea Nitrogen (BUN) and Creatinine Levels

No significant changes were observed in serum SGOT, SGPT, BUN and creatinine levels on completion of the treatment as compared to the baseline (Table 10). A slight decreased in serum ALP level was observed on completion, however, all the values were within the normal range.

Table 10. Serum Glutamic Oxaloacetic Transaminase (SGOT), Glutamic Pyruvic Transaminase (SGPT), Alkaline Phosphatase (ALP), Blood Urea Nitrogen (BUN) and Creatinine Levels

Parameters	Baseline (mean ± SD)	Study Completion (mean ± SD)	Statistical Analyses
SGOT (IU/L)	30.50± 19.67	34.18 ± 22.30	t-value = 2.016, p = 0.050
SGPT (IU/L)	50.50 ± 24.72	53.20±20.95	t-value = 1.151, p = 0.256
ALP (IU/L)	116.41 ± 27.32	110.57 ± 20.17	t-value = 1.816, p = 0.076
BUN (mg/dL)	9.23 ± 3.14	9.32 ± 2.63	t-value = 0.237, p = 0.814
Creatinine (mg/dL)	0.91 ± 0.29	0.89 ± 0.39	t-value = 0.298, p = 0.767

Data are expressed as mean ±S.D.

Effects on Plasma Glucose, Serum Triglycerides (TG) and Serum HDL Cholesterol (HDL) Levels

No significant changes were observed in plasma glucose, serum TG and HDL levels on completion of the treatment as compared to the baseline (Table 11). All the values were within the normal range.

Table 11. Plasma Glucose, Serum Triglycerides (TG) and Serum HDL Cholesterol (HDL) Levels

Parameters	Baseline (mean ± SD)	Study Completion (mean ± SD)	Statistical Analyses
Plasma Glucose (mg/dL)	90.59 ± 14.50	92.48 ± 13.67	t-value = 1.776, p = 0.083
TG (mg/dL)	108.84 ± 48.27	122.45 ± 52.83	t-value = 1.505, p = 0.140
HDL (mg/dL)	47.80 ± 13.68	47.45 ± 9.24	t-value = 0.188, p = 0.852

Data are expressed as mean ± S.D.

Discussion

Polycystic ovary syndrome (PCOS) is a common endocrine system disorder in women of reproductive age. In adolescents, infrequent or absence of menstruation and/or allied difficulties cause serious mental and psychological distress, loss of confidence and anxiety. PCOS has a close association with metabolic disorders/syndrome with a prevalence of insulin resistance in 50-70% subjects, and up to 70% for dyslipidemia (19-24). It is interesting to note that high-fat diet induces obesity and PCOS in rodents (25). Sarray et al. (2015) exhibited the validity of adiponectin-to-leptin and adiponectin-to-resistin ratios as predictors of PCOS (26). In addition, Ezeh et al (2014) demonstrated that compared with controls of similar BMI, women with PCOS demonstrate adverse body composition characterized by increased whole body fat relative to lean mass (a higher F/L ratio), which is associated with differences in metabolic dysfunction between the two groups (27).

Naderpoor et al. (2015) conducted a systematic review and meta-analysis to compare the effect of lifestyle modification and metformin with lifestyle modification ± placebo, and of metformin alone with lifestyle modification ± placebo in PCOS on anthropometric, metabolic, reproductive and psychological outcomes (19). Ranasinha et al. (2015) conducted a statistical modelling and commented that PCOS is more likely to display metabolic clustering in comparison to age and BMI-matched control subjects. Obesity and insulin resistance, but not androgens, are independently and most strongly associated with metabolic syndrome in PCOS (28).

As discussed earlier, several treatment regimen including metformin, cabergoline, myo-inositol,

D-chiro-inositol, combined oral contraceptives including estradiol and non-androgenic progesterone, and aromatase inhibitors are being extensively used for PCOS (6-11). A number of natural products and plant extracts are comparatively much less expensive and demonstrate promising efficacy in the management of PCOS. Efficacy of novel nutraceuticals including *Nardostachys jatamansi, Tribulus terrestris, Urtica diocia*, *Serenoa repens*, *Vitex agnus-castus* and *Foeniculum vulgare* is well documented against PCOS (12-14). Furthermore, dietary fiber, flax seed, fish oil and chromium picolinate are widely used in PCOS formulations (12-14). Most of these phytopharmaceuticals and nutraceuticals are already quite popular in the marketplace.

Our present multi-centric, open label, single arm, non-randomized study of a novel fenugreek seed extract enriched in furostanolic saponins (Furocyst) was conducted in female subjects suffering from PCOS over a period of 90 consecutive days. Fifty subjects were recruited after rigorously following the inclusion and exclusion criteria, and asked to consume 2 capsules of Furocyst over a period of 90 consecutive days.

The reduction in both left and right ovarian volume and the number of ovarian cysts following treatment with Furocyst were monitored using sonographic scan over the period of 90 days. LH, FSH, LH/FSH ratio, and effect of menstrual cycle were recording meticulously.

Plasma glucose levels (fasting glucose), serum triglyceride (TG) and HDL levels, total leukocyte count and hemoglobin levels were also monitored at the beginning and end of 90 days treatment.

To further ascertain the safety of Furocyst over the period of 90 consecutive days, liver function tests including serum glutatamic oxaloacetic transaminase (SGOT), serum glutatamic-pyruvic transaminase (SGPT), serum alkaline phosphatase (ALP) activities were conducted at the beginning and completion of the study at the end of 90 days. Nephrotoxicity was monitored by assessing blood urea nitrogen (BUN) in the beginning and at the end of 90 days of treatment. The potential cardiotoxicity was evaluated by evaluating creatinine in the beginning and at the end of 90 days of treatment. It is important to mention that elevated serum creatinine is associated with increased mortality in hypertensive persons, including the elderly and patients with myocardial infarction. Serum creatinine concentration is associated with major ischemic heart disease and stroke events. Research has demonstrated that elevated serum creatinine may be an independent predictor of all cause of cardiovascular disease mortality.

Encouraging results were obtained in this study. Overall, 94% of patients responded positively to the treatment and surprisingly, 12% of study population got pregnant. Three pregnancies were observed after 30 days, one after 39 days, one after 70 days and another after 84 days of treatment, respectively. Significant improvement in menstrual cycle was also observed following Furocyst treatment. On completion of the study, 71% subjects had regular cycles, 19% reported prolonged cycle and approximately 10% reported primary infertility. None of the subjects reported irregular cycle at the end of dosing schedule.

Left ovary volume was decreased by 17.82% ($p < 0.101$) and right ovary volume was decreased by 28.57% ($p < 0.000$*) in Furocyst-treated subjects. Treated subjects demonstrated reduction in cyst size, 46% subjects showed reduced cyst size while 36% showed no cysts at the end of the study. Significant increases in LH and FSH were observed following Furocyst treatment. A decrease in the LH/FSH ratio was observed, but it was not significant. However, it is very important to mention that generally the ratio of LH and FSH ratio is approximately 1:1 in normal subjects, however, in women with PCOS the LH:FSH ratio is often higher, for example 2:1 or even 3:1 (29). In our investigation, the initial LH/FSH ratio was approximately 3.16, which reduced to 1.61 following the treatment, which is very encouraging.

No increases in the parameters of hepatotoxicity, nephrotoxicity or cardiotoxicity were observed over the period of 90 days of treatment, which demonstrates the broad-spectrum safety of Furocyst. No significant change in hemogram was observed. There was a small but significant increase in hemoglobin level (Hb) following treatment with Furocyst. No significant change in total leukocyte count was observed. No significant changes were observed in plasma glucose (fasting glucose), serum HDL cholesterol and TG levels.

Overall, this human study demonstrates the broad-spectrum safety and efficacy of this Furocyst in the treatment of PCOS.

Competing Interests

AS, MB and DB are engaged in Cepham Research Center, Piscataway, NJ, PK is working in Chemical Resources, Panchkula, India, and Dr. Preuss is a professor at Georgetown University Medical Center, Washington, DC, directed this study. Dr. A.S. Jaipuriar and Dr. Gupta are clinical physicians conducted this clinical study in their clinics, respectively.

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