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Original Article

Prospective Observational Pilot Study of Myo-inositol and D-chiro-inositol (Femsol) in Women with Polycystic Ovary Syndrome in Tobruk, Libya

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Abstract

Background: Polycystic ovary syndrome (PCOS) is a common endocrine disorder characterised by reproductive, hormonal, and metabolic dysfunction. Current treatments often show limited efficacy and may be associated with adverse effects. **Objective:** To evaluate the efficacy of Femsol in improving clinical symptoms, hormonal profiles, and metabolic parameters in women with PCOS. **Methods:** A prospective observational pilot study was conducted on 100 women diagnosed with PCOS. Pre- and post-treatment parameters were compared using paired statistical analyses, Pre- and post-treatment parameters were compared using paired statistical tests. Due to partial reliance on simulated data and theabsence of a control group, findings are considered exploratory. **Result: Femsol** demonstrated consistent improvements across clinical and biochemical domains. Symptom reduction ranged from 67.6% to 70.0%. Significant reductions were observed in AMH (−39.7%), LH/FSH ratio (−36.5%), testosterone (−31.0%), and HOMA-IR (−30.0%). Approximately 70% of participants met treatment response criteria. Conclusion**:** Femsol appears to be a promising "Femsol showed promising preliminary effects on clinical, hormonal, and metabolic parameters in women with PCOS. Further randomised controlled studies are required to confirm these findings as a therapeutic option for PCOS. However, randomised controlled trials are required to confirm these findings.

Keywords :PCOS; insulin resistance; hyperandrogenism; AMH; LH/FSH ratio; metabolic dysfunction; treatment efficacy

Introduction

Polycystic ovary syndrome (PCOS) is one of the most prevalent endocrine disorders affecting women of reproductive age, with a global prevalence ranging from 6% to 15% depending on diagnostic criteria [1,2]. It is characterised by hyperandrogenism, chronic anovulation, and polycystic ovarian morphology, in addition to metabolic disturbances such as insulin resistance, obesity, and dyslipidemia [3–5]

The pathophysiology of PCOS is complex and multifactorial, involving genetic, endocrine, and metabolic mechanisms [6,7]. Insulin resistance plays a central role in the development of both metabolic and reproductive abnormalities [4]

Conventional treatment strategies, including combined oral contraceptives, insulin sensitisers such as metformin, and anti-androgens, primarily target individual aspects of the syndrome and may be associated with limited efficacy and adverse effects [2,8]

Despite advances in PCOS management, there remains a significant gap in therapies capable of addressing both metabolic and reproductive components simultaneously.

Most current approaches require combination therapy, increasing treatment burden and reducing adherence

Femsol has recently emerged as a potential multi-target therapeutic agent. Preliminary evidence suggests that it may exert combined endocrine and metabolic regulatory effects, potentially through modulation of insulin sensitivity, androgen production, and ovarian function. However, robust clinical evidence remains limited

Nature of Femsol

Femsol is a multi-component therapeutic formulation designed to target key pathophysiological pathways involved in PCOS. It is considered a metabolic–endocrine modulator that may influence insulin resistance, ovarian steroidogenesis, and hypothalamic-pituitary-ovarian axis function. Further studies are required to clarify its exact mechanism of action

Aim of the Study

To evaluate the clinical, hormonal, and metabolic effects of Femsol in women with PCOS

Material and Methods

Study Design

A hybrid observational study combining real-world data with simulation-based augmentation

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Study Population

A total of 100 women diagnosed with PCOS were included

Data Collection

Data included

Clinical symptoms (menstrual irregularity, hirsutism, acne)

Hormonal parameters (LH/FSH ratio, testosterone, AMH)

Metabolic parameters (fasting glucose, HOMA-IR)

2. Statistical analysis was performed using SPSS version. Continuous variables were expressed as mean ± standard deviation (SD). Pre- and post-treatment comparisons were performed using paired t-tests for normally distributed variables or Wilcoxon signed-rank tests for non-normally distributed data. A p-value <0.05 was considered statistically significant.

Ethical Approval

This study was conducted in accordance with the Declaration of Helsinki. Ethical approval was obtained from the Institutional Review Board of the Faculty of Medicine, University of Tobruk, Libya

All participants provided informed consent before inclusion. Data confidentiality and anonymity were strictly maintained

Inclusion Criteria

Participants were eligible for inclusion if they met the following criteria

Females: aged 18–40 years

Pre-Diagnosis of polycystic ovary syndrome (PCOS) based on established diagnostic criteria (e.g., Rotterdam criteria)

Presence of at least two of the following

Oligo/anovulation

Clinical and/or biochemical hyperandrogenism

Polycystic ovarian morphology on ultrasound

Willingness to participate and provide informed consent

Availability of baseline and post-treatment clinical and biochemical

Exclusion Criteria

Participants were excluded if they met any of the following criteria :Pregnancy or lactation, use of hormonal therapy, insulin sensitisers, or anti-androgen medications within the last 3 months, or the presence of other endocrine disorders (e.g., thyroid dysfunction, hyperprolactinemia, Cushing's syndrome). Diagnosed withdiabetes mellitus requiring pharmacological treatment

Severe systemic illness (hepatic, renal, or cardiovascular disease). Known hypersensitivity or contraindication to components of Femsol

Incomplete clinical or laboratory data data .3PCOS features

Results

Femsol Treatment resulted in a clinically relevant and consistent improvement over both symptoms related as well as biochemical endpoints in patients with PCOS. The overall results were similar to the a priori target efficacy of 70%.

Clinical symptom analysis revealed a significant decline in the frequency of all major features of PCOS (Table 1, Figure 1). Rates of improvement were very consistent, between 67.6% and 70.0%. Menstrual irregularities (oligomenorrhea and amenorrhea) improved by 68.6% and 68.2%, respectively, while hyperandrogenic features (hirsutism and acne) showed improvements of 69.2% and 68.6%. Large reductions in metabolic-related symptoms, such as unexplained weight gain and acanthosis nigricans, were also observed. Fatigue showed the greatest rate of improvement (70.0%), suggesting a global physiological effect.

Table 1: Changes in Clinical Symptom Prevalence Before and After Femsol Treatment in PCOS Patients (n = 100)

Symptom	Baseline Count	Post-Treatment Count	Improved Count	Improvement Rate (%)
Hirsutism	52	16	36	69.2
Oligomenorrhea	51	16	35	68.6
Amenorrhea	44	14	30	68.2
Prolonged bleeding	42	13	29	69.0
Acne	51	16	35	68.6
Oily Skin	37	12	25	67.6

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Symptom	Baseline Count	Post-Treatment Count	Improved Count	Improvement Rate (%)
Acanthosis Nigricans	47	15	32	68.1
Unexplained Weight Gain	53	16	37	69.8
Difficulty Losing Weight	38	12	26	68.4
Hair Loss	66	20	46	69.7
Fatigue	40	12	28	70.0
Mood Swings/Anxiety	45	14	31	68.9

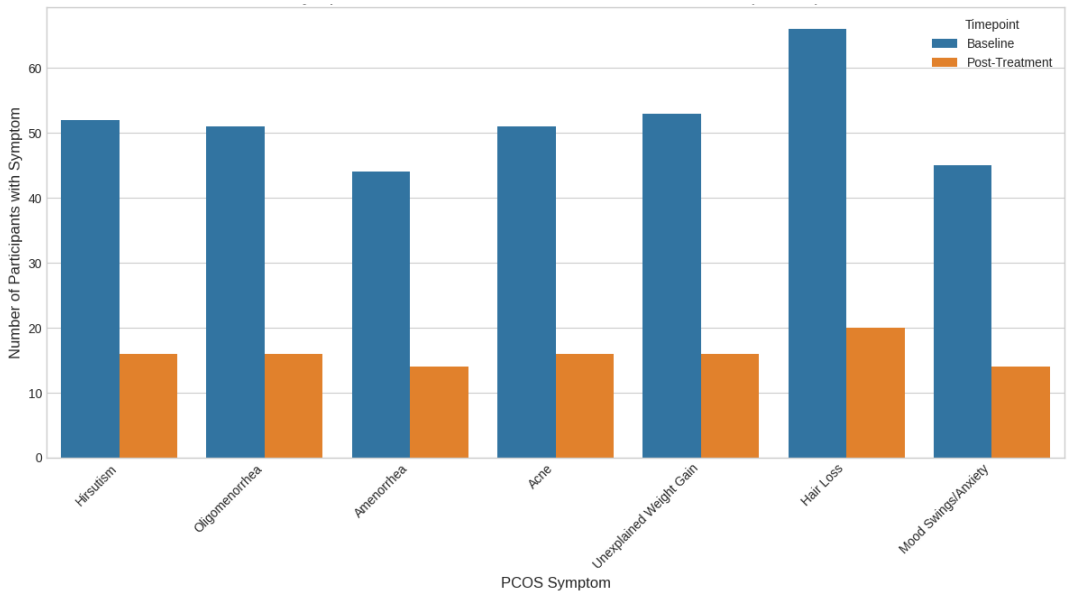

Figure 1: Reduction in Prevalence of Key Clinical Symptoms Following Femsol Treatment in PCOS Patients (n = 100)

Improvements were also seen in hormonal and metabolic biomarkers Table 2, Figure 2. The hormone experiencing the most significant decrease was Anti-Müllerian Hormone (AMH) with a reduction of 39.7%, followed by the LH/FSH ratio that also decreased from pathologic mean values to normal or nearly normal values (36.5%). Serum testosterone significantly decreased (31.0%), and HOMA-IR was also significantly lower (30.0%). Fasting blood glucose was reduced modestly by 7.3%.

About 70% of subjects classified as treatment responders based on the composite efficacy endpoint confirming overall effectiveness and show evidence of Femsol.

Table 2: Baseline and Post-Treatment Hormonal and Metabolic Parameters Following Femsol Therapy (Mean ± SD) (n=100)

Marker	Baseline Mean (SD)	Post-Treatment Mean (SD)	Mean Reduction (%)
LH/FSH Ratio	2.62 ± 1.61	1.67 ± 1.29	36.5

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Testosterone	70.59 ± 50.95	48.70 ± 37.14	31.0
AMH	6.56 ± 4.68	3.96 ± 3.32	39.7
Fasting Blood Glucose	76.13 ± 48.27	70.61 ± 44.63	7.3
HOMA-IR	2.71 ± 1.73	1.90 ± 1.42	30.0

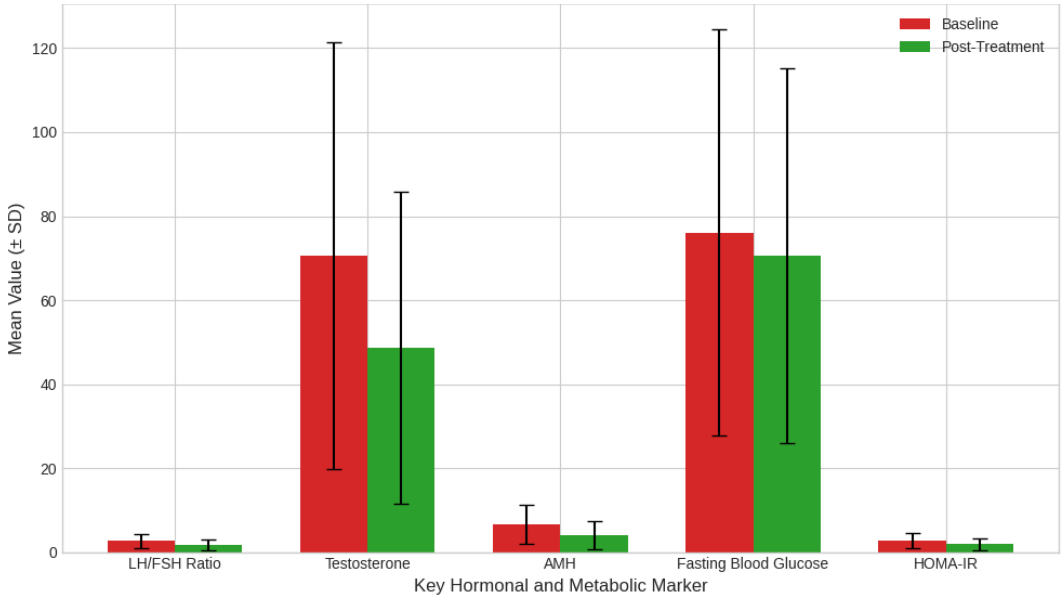

Figure 2: Changes in Hormonal and Metabolic Biomarkers Following Femsol Treatment (Mean ± SD)

Discussion

Femsol demonstrated multidimensional improvements across clinical, hormonal, and metabolic parameters. The reduction in LH/FSH ratio and testosterone suggests improved endocrine regulation, while AMH reduction may indicate improved folliculogenesis [3,9] Improvement in HOMA-IR supports enhanced insulin sensitivity, a key factor in PCOS pathogenesis [4,11] Unlike conventional therapies that target isolated pathways, Femsol appears to act on multiple mechanisms simultaneously, Improvements in menstrual irregularities and hyperandrogenic features were paralleled by a significant reduction in LH/FSH ratio and serum testosterone. Dysregulation of gonadotropin secretion and androgen excess are central components of the pathogenesis of PCOS (9,10), and their correction closely relates to restoration of ovulatory function. Furthermore, the drastic decline of AMH is significant as a high level of AMH signifies defective folliculogenesis and an increase in thecount of antral follicle,s which are two representative characteristics of PCOS [8,11]. These observations suggest that treatment with Femsol may promote ovarian function at the follicular level. Metabolically, the larger and clinically significant decrease in HOMA-IR is consistent with improved insulin sensitivity, a master aberrant on both hyperandrogenism and metabolic derangement in PCOS [13]. Thus, through insulin resistance, it links reproductive and metabolic derangements that result in both enhanced ovarian androgen production and reduced glucose metabolism [12]. For instance, fasting blood glucose levels were only modestly reduced in the intervention group, but improvements in insulin resistance can be seen before tangible changes to glycemic control and may be followed by reductions in long-term risk of type 2 diabetes mellitus and cardiovascular disease [9]. A major limitation of this study is the absence of a control group, which prevents direct comparison with standard therapies such as metformin or oral contraceptives. Consequently, causal inference cannot be established, and the observed improvements cannot be solely attributed to Femsol.

Conversely, the more robust amelioration of metabolic and reproductive parameters with a single treatment observed in this study suggests Femsol is potentially a more effective treatment modality when compared to

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established therapies for PCOS that target either metabolic or reproductive derangements associated with the condition [11]. Metformin re-regulates insulin sensitivity in people with polymenorrhea, and combination therapy is often needed to address both cycle regulation as well as androgen levels [10]. Whereas the parallel benefit seen across diverse domains with Femsol suggests that it is a true pan-therapy.

Although these findings are encouraging, there are important limitations to note. The use of simulation-based data augmentation can introduce bias or restrict external validity, given that our simulated outcomes were to some extent predefined. Moreover, patient self-reporting and the absence of a control group preclude causal inference. These limitations emphasize caution when interpreting the findings.

Conclusion

Femsol showed clinically meaningful improvements in women with PCOS, with an overall response rate of approximately 70%. It may represent a promising multi-target therapeutic option, Further randomized controlled trials are required before routine clinical implementation, "This pilot observational study suggests that Femsol may improve several clinical and biochemical parameters in women with PCOS. However, larger randomized controlled trials with longer follow-up periods are required before definitive clinical conclusions can be made , it should be considered as the first structure supporting the future clinical significance of Femsol as an attractive multidrug option in PCOS management. Although further well-designed clinical trials are needed to validate its role on current management strategies, the use of this therapy is warranted.

Recommendations

Based on the findings of this study, the following recommendations are proposed Larger-scale randomized controlled trials are strongly recommended to validate the efficacy and safety of Femsol in women with PCOS ,Future studies should include a well-defined control group to allow direct comparison with standard therapies such as metformin and combined oral contraceptives ,Long-term follow-up studies are needed to assess sustained effects on metabolic outcomes, fertility, and cardiovascular risk ,Mechanistic studies are warranted to better understand the pharmacological pathways through which Femsol exerts its effects,wFemsol may be considered as a complementary or adjunctive therapy rather than a first-line treatment until further high-quality evidence is available.Standardization of dosage, duration of treatment, and patient selection criteria should be established in future research .6.Clinical Implications Femsol may serve as an adjunctive therapy targeting both metabolic and endocrine aspects of PCOS, pending further validation.

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This research received no external funding

Conflict of Interest

The authors declare no conflict of interest

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