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Abstract

# Treatment with metformin and combination of metformin plus pioglitazone on serum levels of IL-6 and IL-8 in polycystic ovary syndrome: A randomized, clinical trial

**Durr-e-Shehwar Ali1, Mohsin Shah*, Asif Ali, Muhammad Omar Malik, Farhat Rehman**
*Department of Physiology, Institute of Basic Medical Sciences, Khyber Medical University, Peshawar Pakistan*

**Abstract:**
Statement of the Problem: Elevated serum levels of inflammatory mediators reflect low-grade chronic inflammation and have been attributed to be associated with insulin-resistant states. Therefore, insulin-lowering agents have been recommended to improve both reproductive and metabolic aspects of PCOS. This study aimed to compare metformin and combination of metformin plus pioglitazone on menstrual cyclicity, hormonal parameters, insulin resistance and inflammatory biomarkers in women with PCOS. Methodology & Theoretical Orientation: One hundred and six women with PCOS participated in the study. All subjects were randomized in to two-arm interventions. Arm-1: metformin 500 mg (BD) daily. Arm-2: Combined (metformin 500 mg BD and pioglitazone 15 mg BD) for 12 weeks. The primary outcome measure was serum level of IL-6 and IL-8 using ELISA assay. Secondary outcome was insulin resistance; assessed using HOMA-IR. Findings: At baseline women with PCOS had significantly elevated circulating concentrations of IL-6 and IL-8. Treatment decreased IL-6 in both groups, however only the combination group (p= 0.005) had a significant decrease. IL-8 had a significant decrease after treatment in both groups (p= <0.001). HOMA-IR and insulin levels also decreased in both groups (both p= <0.001). Testosterone, FSH and prolactin significantly decreased in both groups. LH also decreased in both groups, however, the change was significant only in the combination group (p=0.013). Both treatment groups were associated with the reduction in menstrual irregularities, sizes of ovaries and number of follicles. Significance: Combination of metformin and pioglitazone therapy was more effective compared to metformin alone in reducing the levels of IL-6 and IL-8 as well as insulin resistance in PCOS. The addition of pioglitazone with metformin had an additional effect on decreasing inflammation and normalizing hormonal imbalance. Thus modified treatment protocols of combination therapy could further improve the outcome.

**Biography:**

Mohsin Shah has expertise in endocrinology and reproductive physiology. Currently Dr. Mohsin is working as assistant professor in the department of Physiology, Institute of Basic Medical Sciences, Khyber Medical University, Peshawar. The main area of his research interest is nanomedicine in conjunction with endocrinology and reproductive physiology. The present clinical trail finds that women with PCOS have significantly increased circulating inflammatory concentrations of IL-6 and IL-8 before treatment and their levels were influenced by treatment

with metformin and pioglitazone combination as demonstrated by decreased IL-6 and IL-8 levels after three months of therapy. The addition of pioglitazone with metformin had an additional effect on decreasing inflammation and normalizing hormonal imbalance. Thus modified treatment protocols of combination therapy could further improve the outcome. The trial has been registerd with ClinicalTrials.gov number, NCT03117517. Clinical Trial Unit, Sciences, Khyber Medical University.

**Recent Publications:**

1. McCartney CR & Marshall JC (2016). Polycystic Ovary Syndrome. New England Journal of Medicine. 374:54-64.
2. Sangeeta S (2012). Metformin and pioglitazone in polycystic ovarian syndrome: A comparative study. Journal of Obstetrics and Gynecology of India. 62:551–556.
3. Duleba AJ & Dokras A (2012). Is PCOS an inflammatory process? Fertility and Sterility. 97:7–12.
4. Zahra M, Shah M, Ali A, & Rahim R (2016). Effects of Metformin on Endocrine and Metabolic Parameters in Patients with Polycystic Ovary Syndrome. Hormone and Metabolic Research 49:103–108.
5. Long X, Li R, Yang Y, & Qiao J (2017). Overexpression of IL-18 in the Proliferative Phase Endometrium of Patients with Polycystic Ovary Syndrome. Reproductive Sciences 24(2):252-257.
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**Webinar on Annual Meet on Maternal & Infant Diseases and Medicine September 18, 2020, Paris, France**

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