Official Title:

Impact of Myo-Inositol vs Combined Myo-Inositol and Metformin Therapy on Conception Rates, Treatment Adherence, and Tolerability in Overweight Women Diagnosed With PCOS: A Randomized Controlled Study

NCT Number: NCT ID not yet assigned

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Background

Polycystic Ovary Syndrome (PCOS) is a common endocrine disorder affecting 18–25% of reproductive age women in Pakistan. Characterized by hyperandrogenism, anovulation, and polycystic ovarian morphology, it is frequently associated with insulin resistance and obesity, particularly in South Asian populations. Compared to Western women, Pakistani women with PCOS often present with higher BMI, earlier onset of symptoms, and more severe metabolic profiles. While pharmacological treatments like metformin and myo-inositol are widely used, there is a lack of locally relevant data comparing their effectiveness, tolerability, and patient adherence, especially in overweight women seeking fertility treatment.

Objective

To compare the effects of myo-inositol alone versus myo-inositol combined with metformin on conception rates, side effect profiles, and treatment adherence among overweight women with PCOS in a Pakistani clinical setting.

Methodology

Study Design: Randomized, open-label, controlled clinical trial

Study Setting: Gynecology OPD and IPD at PAEC general hospital, Islamabad.

Study Population: 120 overweight women (BMI ≥ 25), aged 20–35, diagnosed with PCOS based on Rotterdam Criteria

Intervention Groups:

- Group A: Myo-inositol 4g/day
- Group B: Myo-inositol 4g/day + Metformin 1500mg/day

Duration: 6 months or until confirmed conception

Primary Outcomes: Conception rate, side effect profile, and treatment adherence

Secondary Outcomes: Menstrual regularity and ovulation status

Data Collection: Patient diaries, ultrasound, hormone testing, questionnaires, and pill count

Statistical Tools: SPSS; significance set at $p < 0.05$

Eligibility Criteria

Inclusion Criteria:

- Women aged 20 to 35 years
- BMI ≥25 kg/m²
- Fulfilled at least two of the three Rotterdam criteria
- Attempting to conceive naturally
- No use of hormonal drugs or insulin-sensitizers in the past three months

Exclusion Criteria:

- Endocrine disorders (e.g., diabetes, thyroid dysfunction)
- Hepatic impairment
- Kidney disease
- Gastrointestinal or malabsorption issues (IBS, IBD, celiac disease)
- Known allergies to metformin or inositol
- Pregnant or breastfeeding

Ethical Considerations

The study received ethical approval from the Institutional Review Board. Written informed consent was obtained from all participants. Confidentiality, voluntary participation, and the right to withdraw at any stage were ensured.

Discussion

This study addresses a critical gap in PCOS management research in Pakistan by focusing on the comparative evaluation of two commonly used insulin sensitizers in a population with unique metabolic characteristics. The investigation explores the clinical and practical implications of both therapies in improving fertility while also considering tolerability and adherence—key factors in long-term success, especially in under-resourced healthcare settings. Cultural, socioeconomic, and behavioral factors affecting Pakistani women's access and response to fertility care further underscore the need for context-specific treatment strategies.

Conclusion

There is a need for well-tolerated, effective, and accessible fertility treatments for overweight women with PCOS in Pakistan. This study contributes evidence to guide clinicians in selecting patient-centered treatment options, potentially positioning myo-inositol as a preferred first-line agent due to its favorable safety and adherence profile.

Clinical Implications

In the Pakistani healthcare setting, clinicians may consider initiating treatment with myo-inositol alone for overweight PCOS patients seeking conception, with metformin reserved for cases demonstrating poor metabolic response or persistent ovulatory dysfunction.

Strengths and Limitations

Key strengths include the randomized design and population-specific focus, adding to the limited local data on PCOS. Limitations include the short follow-up duration and reliance on self-reported adherence. Future studies with extended observation periods and objective adherence metrics are recommended.

PCOS Clinical Trial – Data Collection Form

SECTION 1: PARTICIPANT IDENTIFICATION

Patient Name: _____

Date of Enrollment: ___ / ___ / 2025

Assigned Group:

- Group A – Myo-inositol only
- Group B – Myo-inositol + Metformin

SECTION 2: DEMOGRAPHICS

Age (years): _____

Weight (kg): _____

Height (cm): _____

BMI: _____ (calculated)

Marital Status: ☐ Married ☐ Single

Duration of Infertility: _____ years

SECTION 3: CLINICAL HISTORY

- Irregular menstruation: ☐ Yes ☐ No Cycle length: _____ days
- Hirsutism: ☐ Yes ☐ No Score: _____ (Ferriman-Gallwey)
- Acne: ☐ Yes ☐ No Severity: ☐ Mild ☐ Moderate ☐ Severe

- Previous PCOS Treatment: ☐ Yes ☐ No Type: _____

SECTION 4: FOLLOW-UP AND TREATMENT MONITORING

Visit | Side Effects | Compliance (%) | Menstrual Regularity | Ovulation Confirmed | Pregnancy Confirmed

Month 1 _____ _____% ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

Month 2 _____ _____% ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

Month 3 _____ _____% ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

Month 6 / Final _____ _____% ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

SECTION 5: ULTRASOUND & LABORATORY MONITORING

- Confirmed Ovulation Method: ☐ Mid-luteal Progesterone ☐ Ultrasound
- Ultrasound Findings: _____
- Hormonal Tests: FSH: ____ LH: ____ AMH: ____
- Fasting Glucose: ____ mg/dL, Insulin: ____ µU/mL

Participant Information & Consent Form

Study Title: Comparison of Myo-inositol Alone versus Myo-inositol plus Metformin in Overweight Women with PCOS

Principal Investigator: Dr. Maria Amin, Department of Obstetrics and Gynecology, PAEC General Hospital, Islamabad

Why is this study being done?

We want to learn whether myo-inositol alone works as well as myo-inositol plus metformin in helping overweight women with PCOS to conceive. We will also look at side effects, treatment use, and menstrual health.

What will I be asked to do?

- Be randomly placed into one of two groups:
- Group A: Myo-inositol (4 g/day)
- Group B: Myo-inositol (4 g/day) + Metformin (1500 mg/day)

- Take the assigned treatment for six months
- Attend follow-up visits and ultrasound checks
- Report any side effects and your treatment use

Benefits

- You may have improved menstrual cycles, ovulation, and a chance of pregnancy.
- Your participation will help improve treatment options for women with PCOS.

Risks

- Myo-inositol: Usually safe with few side effects.
- Metformin: May cause stomach upset, nausea, or diarrhea.
- No serious risks are expected.

Voluntary Participation

Taking part is your choice. You may stop at any time without affecting your medical care.

Confidentiality

Your information will be kept private. Results will not identify you.

Contact

If you have questions, please contact: Dr. Maria Amin – mariaamin13@yahoo.com

Consent

I have read and understood this information. I agree to take part in this study.

Participant's Name: _____

Signature/Thumbprint: _____

Date: _____

Investigator's Signature: _____

Date: _____