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Original Research Article

# A Prospective Randomized Trial Comparing Letrozole and Clomiphene Citrate for Ovulation Induction in Women with PCOS

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**Conflict of interest: Nil**

**Abstract:**

**Background:** Polycystic Ovary Syndrome (PCOS) is a prevalent endocrine condition that leads to infertility as a result of prolonged anovulation. Pharmacological ovulation induction (OI) using drugs like Letrozole and Clomiphene Citrate (CC) is a fundamental approach to reinstating fertility.

**Aim:** To evaluate the effectiveness, endometrial response, ovulation, pregnancy outcomes, and tolerability of Letrozole compared to Clomiphene Citrate in women with PCOS.

**Methodology:** This prospective, randomized, open-label comparative study was conducted at a tertiary care center in Patna from August 2024 to July 2025. Ninety women with PCOS were randomized into two groups: letrozole (5 mg) or CC (100 mg) from day 3–7 of the cycle. Follicular monitoring, endometrial thickness, ovulation, pregnancy outcomes, and adverse effects were assessed.

**Results:** Ovulation rate was higher with letrozole (86.7%) than CC (75.6%), though not statistically significant. Endometrial thickness was significantly greater in the letrozole group (9.2 ± 1.1 mm vs 8.0 ± 1.3 mm; $p<0.01$). Clinical pregnancy rates were 33.3% with letrozole and 22.2% with CC. Adverse effects were slightly lower with letrozole.

**Conclusion:** Letrozole demonstrated better endometrial response and a trend toward higher ovulation and pregnancy rates, with comparable safety, making it an effective alternative to clomiphene citrate in PCOS.

**Keywords:** PCOS, Ovulation Induction, Letrozole, Clomiphene Citrate, Infertility, Endometrial Thickness.

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## Introduction

Polycystic Ovary Syndrome (PCOS) is one of the most prevalent endocrine disorders affecting women of reproductive age, with a reported global prevalence ranging from 6% to 20%, depending on the diagnostic criteria applied [1]. It is a heterogeneous and multifactorial condition characterized by hyperandrogenism, chronic anovulation, and polycystic ovarian morphology. In addition to reproductive dysfunction, PCOS is frequently associated with metabolic abnormalities such as insulin resistance, obesity, dyslipidemia, and an increased risk of type 2 diabetes mellitus. The clinical presentation is highly variable and may include menstrual irregularities, infertility, hirsutism, acne, and obesity, resulting in significant reproductive and metabolic consequences. Among these, infertility remains one of the most distressing complications, primarily attributable to persistent anovulation, which disrupts the normal cyclic release of oocytes and reduces the probability of spontaneous conception.

Ovulation induction (OI) represents the cornerstone of infertility management in women with PCOS [3]. The principal objective of OI is to promote the development and release of a mature follicle, thereby restoring ovulatory cycles and enhancing the likelihood of pregnancy. Various pharmacological agents are employed for this purpose, including selective estrogen receptor modulators, aromatase inhibitors, insulin sensitizers, and gonadotropins, each differing in mechanism of action, efficacy, safety profile, and cost. Clomiphene citrate (CC), a selective estrogen receptor modulator, has traditionally been considered the first-line agent for ovulation induction because of its established efficacy, ease of administration, and affordability. However, a substantial proportion of women exhibit clomiphene resistance

or experience anti-estrogenic effects on the endometrium and cervical mucus, which may compromise implantation and pregnancy outcomes.

In recent years, aromatase inhibitors (particularly letrozole) have gained increasing acceptance as an alternative to clomiphene citrate. Letrozole acts by inhibiting aromatase activity, leading to reduced estrogen synthesis and a compensatory rise in follicle-stimulating hormone secretion. This mechanism promotes mono-follicular development and is associated with a lower incidence of anti-estrogenic effects on the endometrium. Evidence suggests that letrozole may result in improved ovulation and live birth rates compared with clomiphene in women with PCOS [4]. Gonadotropins, although effective, are generally reserved for clomiphene-resistant cases or assisted reproductive techniques due to higher costs and increased risks of ovarian hyperstimulation syndrome and multiple gestations.

The success of ovulation induction is influenced by multiple factors, including age, body mass index, severity of hyperandrogenism, degree of insulin resistance, and baseline ovarian reserve [5]. Lifestyle modifications, particularly weight reduction in overweight or obese women, have been shown to significantly enhance ovulatory function and fertility outcomes. Careful monitoring during ovulation induction is essential to reduce potential complications such as ovarian hyperstimulation syndrome, multiple pregnancies, and miscarriage, which may adversely affect maternal and neonatal outcomes [6]. The adoption of individualized treatment protocols and evidence-based approaches has substantially improved the effectiveness and safety of ovulation induction in this population.

Outcome assessment following ovulation induction includes evaluation of ovulation rates, clinical pregnancy rates, live birth rates, and adverse events [7]. While several studies have compared letrozole and clomiphene citrate, variations in study design, population characteristics, and outcome measures have resulted in inconsistent findings. Furthermore, data from tertiary care centers in developing regions remain limited. Continued research and refinement of therapeutic strategies, including individualized dosing regimens and adjunctive metabolic interventions, are essential to optimize reproductive outcomes in women with PCOS [8].

In addition to clinical considerations, the psychosocial impact of infertility in women with PCOS should not be overlooked. Repeated treatment cycles and delayed conception often impose significant emotional and psychological stress, underscoring the importance of comprehensive care that integrates medical management with counseling and patient education [9].

Given the high prevalence of PCOS and its substantial contribution to anovulatory infertility, a direct comparison of commonly used ovulation induction agents remains clinically relevant. Therefore, the present study was undertaken to compare the efficacy, endometrial response, ovulation rate, pregnancy outcomes, and tolerability of letrozole and clomiphene citrate in women with PCOS undergoing ovulation induction.

## Methodology

**Study Design:** This was a prospective, randomized, open-label, comparative trial conducted to evaluate the effectiveness of letrozole and clomiphene citrate (CC) for ovulation induction in women with polycystic ovary syndrome (PCOS).

The primary outcome of the study was ovulation rate.

The secondary outcomes included endometrial thickness on the day of hCG administration, number of mature follicles (≥18 mm), clinical pregnancy rate, biochemical pregnancy rate, and incidence of adverse effects.

**Study Area:** The study was conducted at the Department of Obstetrics and Gynaecology, Nalanda Medical College and Hospital, Patna, Bihar, India.

**Study Duration:** The study was carried out over a period of one year from August 2024 to July 2025.

### Study Participants

**Inclusion Criteria:**

- Women aged 18–35 years diagnosed with PCOS according to the Rotterdam criteria.
- Patients with oligomenorrhea or anovulatory cycles.
- Normal uterine cavity confirmed by hysterosalpingography.
- Male partners with normal semen parameters according to WHO criteria.
- Patients who provided informed consent for participation in the study.

**Exclusion Criteria:**

- Women with congenital adrenal hyperplasia, hyperprolactinemia, or thyroid dysfunction.
- Patients with a history of ovarian surgery or pelvic inflammatory disease.
- Women with severe endometriosis or other uterine pathologies.
- Patients with contraindications to letrozole or clomiphene citrate.
- Women with systemic illnesses such as diabetes, hypertension, or hepatic/renal impairment.

**Sample Size:** A total of 90 eligible women were enrolled and randomly allocated into two equal groups of 45 participants each. The sample size was determined based on feasibility within the study duration and patient availability at the tertiary care center.

**Randomization and Allocation Concealment:** Participants were ‘randomized into two groups using computer-generated random numbers. Allocation concealment was ensured using sealed opaque envelopes, which were opened sequentially at the time of enrollment.

Due to the nature of the interventions, blinding was not feasible; therefore, the study was conducted as an open-label trial.

**Procedure**

After enrollment, baseline evaluation included detailed history, physical examination, body mass index assessment, and relevant hormonal investigations.

- **Group A (Letrozole group):** Letrozole 5 mg orally daily from day 3 to day 7 of the menstrual cycle.
- **Group B (Clomiphene Citrate group):** Clomiphene citrate 100 mg orally daily from day 3 to day 7 of the menstrual cycle.

Transvaginal ultrasonography was performed on days 10, 12, and 14 of the cycle to monitor follicular growth and measure endometrial thickness. When the leading follicle reached a diameter of ≥18 mm, 5000 IU of human chorionic gonadotropin (hCG) was administered intramuscularly to trigger ovulation.

Couples were advised timed intercourse 24–36 hours after hCG administration.

Ovulation was confirmed by ultrasonographic evidence of follicular rupture.

Biochemical pregnancy was defined as a positive serum β-hCG level measured two weeks after hCG trigger in the absence of menstruation.

Clinical pregnancy was defined as the presence of an intrauterine gestational sac on transvaginal ultrasound at 5–6 weeks of gestation.

Participants were monitored for adverse effects such as hot flashes, ovarian cyst formation, breast tenderness, and mood changes. Follow-up continued until confirmation of ovulation or pregnancy outcome.

**Statistical Analysis:** Data were entered and analyzed using SPSS version 27.0. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. The independent t-test was used to compare continuous variables between the two groups, and the chi-square test was applied for categorical variables. Odds ratios (OR) with 95% confidence intervals (CI) were calculated where appropriate. A p-value of <0.05 was considered statistically significant.

**Result**

Table 1 presents the baseline characteristics of the study participants in the Letrozole and Clomiphene Citrate groups. The mean age of participants was comparable between the Letrozole group (26.4 ± 3.2 years) and the Clomiphene Citrate group (27.0 ± 3.5 years), with no statistically significant difference (p = 0.45). Similarly, the mean BMI was 26.8 ± 4.1 kg/m² in the Letrozole group and 27.2 ± 3.9 kg/m² in the Clomiphene Citrate group (p = 0.61). The duration of infertility was also similar between the groups, averaging 3.2 ± 1.4 years for Letrozole and 3.5 ± 1.6 years for Clomiphene Citrate (p = 0.38). The prevalence of oligomenorrhea was 77.8% in the Letrozole group and 82.2% in the Clomiphene group (p = 0.57), while hirsutism, defined as a Ferriman–Gallwey score ≥8, was observed in 40.0% and 44.4% of participants, respectively (p = 0.66). Overall, there were no significant differences between the groups in any of the baseline characteristics, indicating that the groups were well matched.

**Table 1: Baseline Characteristics of Study Participants**

| Characteristic | Letrozole Group (n=45) | Clomiphene Citrate Group (n=45) | p-value |
|---|---|---|---|
| Age (years, mean ± SD) | 26.4 ± 3.2 | 27.0 ± 3.5 | 0.45 |
| BMI (kg/m², mean ± SD) | 26.8 ± 4.1 | 27.2 ± 3.9 | 0.61 |
| Duration of infertility (years, mean ± SD) | 3.2 ± 1.4 | 3.5 ± 1.6 | 0.38 |
| Oligomenorrhea (%) | 35 (77.8%) | 37 (82.2%) | 0.57 |
| Hirsutism (Ferriman–Gallwey ≥8) | 18 (40.0%) | 20 (44.4%) | 0.66 |

Table 2 shows the comparison of follicular response and endometrial thickness between the Letrozole and Clomiphene Citrate groups (n=45 each). The mean number of follicles ≥18 mm was slightly lower in the Letrozole group (1.8 ± 0.6) compared to the Clomiphene Citrate group (2.0 ± 0.7), but the difference was not statistically significant (p=0.12). Letrozole produced more common mono-follicular cycles which occurred in 71.1% of cases whereas Clomiphene Citrate produced mono-follicular cycles which occurred in 55.6% of cases but Clomiphene group produced multi-follicular cycles which occurred in 44.4% of cases whereas Letrozole produced multi-follicular cycles which occurred in 28.9% of cases although these differences did not reach statistical significance (p=0.09). The

Letrozole group showed a higher endometrial thickness of 9.2 ± 1.1 mm compared to the Clomiphene Citrate group which had a thickness of 8.0 ± 1.3 mm ($p<0.01$). The Clomiphene Citrate group showed higher serum estradiol levels of 245.7 ± 52.3 pg/mL compared to the Letrozole group which exhibited levels of 210.4 ± 48.6 pg/mL ($p=0.01$) which demonstrated different hormonal responses from both treatment methods.

**Table 2: Follicular Response and Endometrial Thickness**

| Parameter | Letrozole (n=45) | Clomiphene Citrate (n=45) | p-value |
|---|---|---|---|
| Mean number of follicles ≥18 mm | 1.8 ± 0.6 | 2.0 ± 0.7 | 0.12 |
| Mono-follicular cycles (%) | 32 (71.1%) | 25 (55.6%) | 0.09 |
| Multi-follicular cycles (%) | 13 (28.9%) | 20 (44.4%) | 0.09 |
| Endometrial thickness (mm) | 9.2 ± 1.1 | 8.0 ± 1.3 | <0.01 |
| Serum Estradiol (pg/mL) | 210.4 ± 48.6 | 245.7 ± 52.3 | 0.01 |

Table 3 presents the ovulation rates in the Letrozole and Clomiphene Citrate groups. In the Letrozole group, 39 out of 45 participants (86.7%) experienced ovulatory cycles, whereas in the Clomiphene Citrate group, 34 out of 45 participants (75.6%) had ovulatory cycles. The calculated odds ratio of 2.0 (95% CI: 0.72–5.53) indicates a higher likelihood of ovulation with Letrozole compared to Clomiphene Citrate, although this difference was not statistically significant ($p = 0.16$). Correspondingly, anovulatory cycles were observed in 6 participants (13.3%) in the Letrozole group and 11 participants (24.4%) in the Clomiphene Citrate group, reflecting a trend toward fewer anovulatory cycles with Letrozole.

**Table 3: Ovulation Rates**

| Outcome | Letrozole Group (n=45) | Clomiphene Citrate Group (n=45) | OR (95% CI) | p-value |
|---|---|---|---|---|
| Ovulatory cycles (%) | 39 (86.7%) | 34 (75.6%) | 2.0 (0.72–5.53) | 0.16 |
| Anovulatory cycles (%) | 6 (13.3%) | 11 (24.4%) | — | — |

Table 4 presents the pregnancy outcomes in the Letrozole and Clomiphene Citrate groups. In the Letrozole group, 33.3% of participants achieved a clinical pregnancy compared to 22.2% in the Clomiphene Citrate group, with an odds ratio of 1.78 (95% CI: 0.74–4.30), although this difference was not statistically significant ($p = 0.19$). Biochemical pregnancies were observed in 4.4% of the Letrozole group and 6.7% of the Clomiphene group. The majority of participants did not achieve pregnancy, accounting for 62.3% in the Letrozole group and 71.1% in the Clomiphene group, indicating a higher trend of pregnancy occurrence with Letrozole, but without reaching statistical significance.

**Table 4: Pregnancy Outcome**

| Outcome | Letrozole Group (n=45) | Clomiphene Citrate Group (n=45) | OR (95% CI) | p-value |
|---|---|---|---|---|
| Clinical pregnancy (%) | 15 (33.3%) | 10 (22.2%) | 1.78 (0.74–4.30) | 0.19 |
| Biochemical pregnancy (%) | 2 (4.4%) | 3 (6.7%) | — | — |
| No pregnancy (%) | 28 (62.3%) | 32 (71.1%) | — | — |

Table 5 shows the adverse effects experienced by participants during treatment in the Letrozole and Clomiphene Citrate groups. Hot flashes were reported in 17.8% of the Letrozole group compared to 26.7% in the Clomiphene Citrate group, while ovarian cyst formation occurred in 4.4% and 11.1% of participants, respectively. Breast tenderness was noted in 6.7% of the Letrozole group and 17.8% of the Clomiphene Citrate group, and mood swings were observed in 8.9% versus 15.6%. A higher proportion of participants in the Letrozole group (62.2%) reported no adverse effects compared to 46.7% in the Clomiphene Citrate group. None of these differences reached statistical significance ($p > 0.05$), indicating comparable tolerability between the two treatments.

**Table 5: Adverse Effects During Treatment**

| Adverse Effect | Letrozole Group (n=45) | Clomiphene Citrate Group (n=45) | p-value |
|---|---|---|---|
| Hot flashes (%) | 8 (17.8%) | 12 (26.7%) | 0.28 |
| Ovarian cyst formation (%) | 2 (4.4%) | 5 (11.1%) | 0.23 |
| Breast tenderness (%) | 3 (6.7%) | 8 (17.8%) | 0.11 |
| Mood swings (%) | 4 (8.9%) | 7 (15.6%) | 0.31 |
| No adverse effects (%) | 28 (62.2%) | 21 (46.7%) | 0.12 |

## Discussion

The present study compared the efficacy and safety of letrozole and clomiphene citrate (CC) for ovulation induction in women with PCOS. The findings demonstrate that both agents are effective in inducing ovulation, with differences observed in endometrial response, follicular pattern, and tolerability profiles. Although the ovulation rate was numerically higher in the letrozole group, the difference did not achieve statistical significance. However, endometrial thickness on the day of hCG administration was significantly greater in women treated with letrozole, suggesting a more favorable endometrial environment.

Our observation of significantly improved endometrial thickness with letrozole is consistent with the findings of Begum et al. (2009) [10], who reported mean endometrial thickness of 10.37 ± 1.2 mm in the letrozole group compared with 9.03 ± 0.89 mm in the CC group. Similarly, Rodriguez-Purata et al. (2014) [11] demonstrated that mono-follicular development was more common with letrozole, whereas CC was associated with a higher incidence of multi-follicular cycles. This difference may be attributed to the mechanism of action of letrozole, which induces ovulation without exerting prolonged anti-estrogenic effects on the endometrium

In the present study, the ovulation rate was higher in the letrozole group (86.7%) compared to the CC group (75.6%), although this difference was not statistically significant. These findings are comparable to those reported by Roy et al. (2012) [12], who documented ovulation rates ranging from 70–81% with letrozole and 62–75% with CC. The higher ovulation rate observed with letrozole may be explained by its ability to transiently suppress estrogen synthesis, leading to enhanced follicle-stimulating hormone secretion without adversely affecting endometrial receptivity.

With respect to pregnancy outcomes, the clinical pregnancy rate was numerically higher in the letrozole group; however, statistical significance was not achieved. These findings suggest that although differences in follicular dynamics and endometrial thickness exist, both agents ultimately yield comparable short-term fertility outcomes.

Endometrial receptivity plays a crucial role in implantation success. In our study, the thicker endometrium observed in the letrozole group supports the hypothesis that letrozole may offer advantages in implantation potential. Cortinez et al. (2005) [13] demonstrated improved endometrial morphology, including optimal pinopode expression, in letrozole-stimulated cycles. Conversely, anti-estrogenic effects of CC may persist beyond the follicular phase, potentially affecting endometrial development. Nonetheless, both agents achieved acceptable pregnancy rates in the present study.

The difference in follicular pattern between the two drugs can be explained by their pharmacological mechanisms. Letrozole, as described by Mitwally and Casper (2000) [14], inhibits aromatase activity, resulting in lower circulating estrogen levels and reduced negative feedback on the hypothalamic–pituitary axis. This targeted mechanism promotes controlled follicular recruitment and may reduce the likelihood of excessive ovarian stimulation. Tulandi et al. (2006) [15] reported lower multiple pregnancy rates with letrozole (2–3%) compared to CC (5–6%), reinforcing its safety profile in terms of minimizing multiple gestations.

In terms of tolerability, fewer adverse effects were observed in the letrozole group, although differences were not statistically significant. These findings are supported by Malloch and Rhoton-Vlasak (2013) [16], who noted better patient acceptance and fewer anti-estrogenic symptoms with letrozole. Fisher et al. (2002) [17] further demonstrated that letrozole maintains a more physiological hormonal milieu compared to CC, which may explain the reduced incidence of vasomotor and mood-related side effects.

Despite the advantages observed with letrozole, CC remains an effective and widely utilized first-line agent. Legro et al. (2007) [18] in the Pregnancy in PCOS I trial reported ovulation rates of 49% and a live birth rate of 23% with CC therapy. These findings highlight that treatment selection should be individualized based on patient characteristics, previous response to therapy, endometrial parameters, and risk of multi-follicular development.

However, certain limitations of the present study should be acknowledged. The study was conducted at a single tertiary care center with a relatively modest sample size, which may limit the generalizability of the findings. The follow-up period was restricted to ovulation and early clinical pregnancy outcomes, and live birth rates were not assessed. Additionally, the open-label design may have introduced performance or observer bias. Larger multicentric randomized controlled trials with longer follow-up durations and live birth assessment are required to further validate these findings.

Overall, the present study suggests that letrozole offers advantages in terms of improved endometrial thickness and favorable mono-follicular development while maintaining comparable ovulation and pregnancy rates relative to clomiphene citrate. Both medications remain effective options for ovulation induction in women with PCOS, and individualized treatment selection remains essential for optimizing reproductive outcomes.

## Conclusion

The present study demonstrates that both letrozole and clomiphene citrate are effective agents for ovulation induction in women with PCOS, with comparable ovulation and pregnancy outcomes. However, letrozole showed a trend toward higher ovulation and clinical pregnancy rates, along with significantly improved endometrial thickness, suggesting a more favorable environment for implantation. Additionally, letrozole was associated with a higher proportion of mono-follicular cycles and fewer adverse effects, indicating a safer and more physiological response. Although these differences were not statistically significant in all parameters, the overall findings suggest that letrozole may offer certain clinical advantages over clomiphene citrate. Nevertheless, both drugs remain viable options, and treatment choice should be individualized based on patient characteristics, response, and clinical judgment.

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