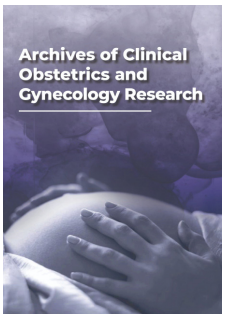
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Short Communication



Integrated Clinical Evidence for Celine® in Women with Polyendocrine Metabolic Ovarian Syndrome (PMOS): From Metabolic Correction to Improved Fertility

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Abstract

Background: *Polyendocrine metabolic ovary syndrome (PMOS) is the most common endocrine disorder affecting women of reproductive age and represents a leading cause of anovulatory infertility. Beyond reproductive dysfunction, PMOS is characterized by insulin resistance, oxidative stress, chronic low-grade inflammation, and hyperandrogenism, all of which contribute to impaired folliculogenesis and reduced fertility. Celine® is a nutraceutical formulation combining myo-inositol, alpha-lipoic acid, and N-acetylcysteine, three compounds with complementary insulin-sensitizing and antioxidant properties. Several clinical studies have evaluated its use in different PMOS populations; however, the available evidence has not previously been synthesized into a single comprehensive review.*

Objective: *To integrate and critically evaluate the published clinical evidence on Celine® across different stages of PMOS management, including metabolic control, restoration of ovulation, and assisted reproductive technology (ART) outcomes.*

Methods: *A narrative integrated evidence review was performed using all three currently published clinical studies evaluating Celine® in women with PMOS. Three clinical investigations involving approximately 1,000 women were included: two randomized controlled trials and one prospective chart review. Evidence was synthesized descriptively according to major clinical outcome domains rather than statistically pooled because of differences in study design, patient populations, interventions, comparators, and outcome definitions.*

Results: *Across all included studies, Celine®-containing regimens consistently demonstrated favorable effects on reproductive and metabolic outcomes. Reported benefits included improvements in insulin resistance and glycemic control, menstrual regularity, ovulation, pregnancy rates, follicular development, mature oocyte yield, embryo quality, and ovarian stimulation efficiency during ART. Although outcome measures were heterogeneous and therefore unsuitable for formal meta-analysis, the consistency of effect direction across complementary clinical settings supports the biological plausibility of the intervention and suggests potential benefits throughout the continuum of PMOS management.*

Conclusions: *The currently available evidence indicates that Celine® may represent a promising adjunctive therapeutic strategy for women with PMOS by simultaneously targeting the metabolic disturbances and reproductive dysfunction underlying the disorder. While the consistency of findings across the available studies is encouraging, the evidence remains limited by heterogeneous study designs and the absence of independent replication. Additional multicenter, adequately powered randomized controlled trials are required to confirm these findings, establish long-term reproductive outcomes, and define the optimal place of Celine® within contemporary PMOS management.*

Introduction

This document consolidates three published studies on Celine®, a combination nutraceutical containing myo-inositol (MI), alpha-lipoic acid (ALA), and N-acetylcysteine (NAC), used as an adjunct in the management of polyendocrine ovarian syndrome (PMOS). The goal is to describe, side by side, what each study tested, what it found, and how consistent the findings are — while being explicit about where the evidence is thin, non-comparable, or subject to conflict of interest.

Three primary studies are included:

- **Study A:** Elfarjani & Choueiry (2024). Effect of Myo-Inositol in Combination with Alpha-Lipoic Acid and Cysteine (Celine™) Based Co-Treatment on Oocyte Quality in Women with PCOS Undergoing Assisted Reproductive Technology. Japan Journal of Research.

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- **Study B:** Elfarjani & Choueiry (2025). Effect of Myoinositol in Combination with Alpha-Lipoic Acid and N-acetylcysteine (Celine®) on Ovulation and Pregnancy Rates in Clomiphene-Resistant Women with PCOS: A Prospective Chart Review. Archives of Clinical Obstetrics and Gynecology Research, 4(1):25-04.
- **Study C:** Yahea, Elsayed, Elgendy & Choueiry (2025). Myoinositol: The New Challenge in Treatment of Polycystic Ovary (PCOS) with Infertility. Archives of Clinical Obstetrics and Gynecology Research, 4(1):25-03.

Overview of the Three Studies

	Study A — Elfarjani & Choueiry, 2024 (Oocyte Quality)	Study B — Elfarjani & Choueiry, 2025 (Ovulation/Pregnancy)	Study C — Yahea et al., 2025 (Metabolic/Infertility)
Journal	Japan Journal of Research	Archives of Clinical Obstetrics and Gynecology Research	Archives of Clinical Obstetrics and Gynecology Research
Design	Randomized controlled trial	Retrospective/prospective chart review — Single arm (no control group)	Randomized controlled trial
Setting	Teaching Assistance Reproductive Technology Hospital, Benghazi, Libya	Teaching Assistance Reproductive Technology Hospital, Benghazi, Libya (Jan–Jun 2019)	Tobruk Medical Center, Tobruk, Libya (Jan 2018–Jan 2022)
Population	n=100, PMOS women 20–40y undergoing ART	n=100, CC-resistant PMOS women 18–37y (subgroup n=63)	n=800, PMOS with infertility + confirmed insulin resistance, 18–42y
Intervention	Celine® (MI+ALA+NAC) + folic acid + standard ART, vs folic acid + standard ART	Celine® alone (2 cycles); non-responders then Celine®+clomiphene citrate (1 cycle)	Celine® + metformin 850mg, vs metformin 850mg alone
Primary outcome(s)	Follicle count, oocytes retrieved, mature (MII) oocytes, embryo quality	Cumulative ovulation rate	Glucose/insulin levels; secondary: ovulation, pregnancy, hyperandrogenic signs
Key result direction	Favors Celine® group on all reported oocyte/embryo measures ($p<0.05$–0.005)	37% ovulation with Celine® alone; 82% cumulative with add-on CC; 43% cumulative pregnancy	Favors Celine®+metformin over metformin alone on all 8 reported measures ($p<0.001$)

Study-by-Study Summaries

Study A — Oocyte quality in women undergoing ART

This was a randomized trial of 100 women with PMOS (aged 20–40) undergoing assisted reproductive technology, allocated 50:50 to Celine® (MI+ALA+NAC) plus folic acid plus standard ART, or folic acid plus standard ART alone. The Celine® group showed a significantly greater number of large preovulatory follicles, more oocytes retrieved, more mature (MII) oocytes, and better embryo quality ($p<0.05$), alongside a shorter ovarian stimulation duration, lower gonadotropin dose requirement, and a higher pregnancy rate ($p<0.005$). These findings suggest that optimization of the ovarian microenvironment before controlled ovarian stimulation may translate into improved laboratory and clinical outcomes. Accordingly, Celine® may be considered as an adjunctive pre-treatment in women preparing for IVF or other assisted reproductive procedures, particularly in those with underlying metabolic disturbances or previous suboptimal ovarian response. That trial was registered: (PACTR202401759325189).

Study B — Ovulation and pregnancy in clomiphene-resistant PMOS

This was a chart review of 100 women with clomiphene citrate (CC)-resistant PMOS who were started on Celine® alone for two cycles; the 63 who remained anovulatory then received Celine® plus CC for a further cycle. There was no comparison group of any kind (no placebo, no untreated cohort, no historical control cohort analyzed statistically). Spontaneous ovulation occurred in 37% on Celine® alone and 71% of the subgroup subsequently given Celine®+CC, for a cumulative ovulation rate of 82%. Clinical pregnancy occurred in 49% of ovulators in the main group and 38% of the Celine®+CC subgroup, with the authors reporting a cumulative clinical pregnancy rate of 43%. These observations suggest that correction of the underlying metabolic and oxidative abnormalities before pharmacological ovulation induction may improve ovarian responsiveness. Rather than replacing established ovulation-inducing therapies, pre-treatment with Celine® may therefore function as a biological priming strategy that enhances their effectiveness

Study C — Metabolic and reproductive outcomes with Celine®+metformin vs. metformin alone

This was the largest of the three studies: a randomized trial of 800 women with PMOS, infertility, and confirmed insulin resistance, comparing Celine® (myo-inositol 2000mg/day) plus metformin 850mg (n=400) against metformin 850mg alone (n=400) over 8 months. The combination group showed significantly greater improvement in fasting glucose and insulin levels, acne, hirsutism, body weight, menstrual cycle regularity, follicle diameter on ultrasound, and pregnancy rate (561/800 pregnancies overall; 347/400 in the combination group vs. 214/400 in the metformin-alone group; $p<0.00001$). This is the only one of the three studies to compare Celine® against an active standard-of-care agent rather than just folic acid or absent comparator. These findings suggest that Celine® may be considered early in the management of women with insulin-resistant PMOS, particularly when metabolic dysfunction represents a major component of the clinical presentation.

Thematic Synthesis Across Outcome Domains

Rather than a single pooled statistic, the findings are grouped below by outcome domain, noting which studies contribute to each and how comparable they actually are.

Ovulation restoration

Reported only in Studies B and C, in different populations (CC-resistant vs. general insulin-resistant infertility) and with different comparators (none vs. metformin). Both report improvement associated with Celine® use, but the absolute rates (37–71% in Study B; not separately broken out as a rate in Study C's Table 4, where 532/800 improved on folliculometry) are not on a common scale and should not be averaged.

Pregnancy / clinical outcomes

All three studies report a pregnancy-related outcome, making this the closest thing to a shared endpoint — but the definitions and denominators differ across studies (pregnancy among ART cycles in Study A; cumulative clinical pregnancy among CC-resistant anovulatory women in Study B; pregnancy over 8 months of combination therapy in Study C). Directionally, all three favor Celine®-containing regimens over the comparator used in that study. This directional consistency is worth noting, but it is not equivalent to a validated combined effect size, given the differences in denominators and follow-up duration.

Oocyte and embryo quality (ART-specific)

Reported only in Study A. No other study measured oocyte count, maturity, or embryo grading, so this outcome has a single-study evidence base.

Metabolic parameters (glucose, insulin)

Reported only in Study C (n=800), which is also the largest and best-powered of the three studies for this outcome.

Hyperandrogenic and clinical signs (acne, hirsutism, body weight, cycle regularity)

Also reported only in Study C. The authors note that Celine®'s saw palmetto (Serenoa repens) component may contribute to the anti-androgenic skin effects observed, which is a plausible but unverified mechanistic explanation offered by the author group however not tested against a saw-palmetto-free version of the product.

Consistency and Coherence of Findings

Considered together, the three studies are directionally consistent: none reports a null or unfavorable result for Celine®, and the general pattern (improved ovarian/metabolic parameters, improved ovulation, improved pregnancy rate) is coherent with the known mechanisms of myo-inositol, ALA, and NAC as insulin-sensitizing and antioxidant agents, which is independently supported by the broader (non-Celine®-specific) literature cited within these papers' own reference lists. This mechanistic plausibility is a genuine strength.

While the consistency of the observed effects is very encouraging, it should not be interpreted as a substitute for independent replication. More well-designed randomized controlled trials are needed to confirm these findings, establish causality, and further elucidate the biological mechanisms underlying the therapeutic effects of Celine®.

Limitations of the Evidence Base

- Heterogeneous designs: one RCT with a common comparator (Study A/ folic acid), one uncontrolled chart review (Study B), and one RCT against an active comparator (Study C) — not statistically combinable.
- Heterogeneous populations: general ART candidates, CC-resistant anovulatory women, and insulin-resistant infertility patients are three different clinical phenotypes.
- Study B has no control group, so improvements cannot be firmly attributed to Celine® alone rather than to mixed effects of spontaneous ovulation, regression to the mean, or the subsequent addition of clomiphene citrate to Celine®.
- Blinding is not clearly described for Studies A and C, raising the possibility of observer or reporting bias in outcomes such as folliculometry or symptom improvement.
- Small number of studies: three studies is a limited base from which to draw generalizable conclusions.

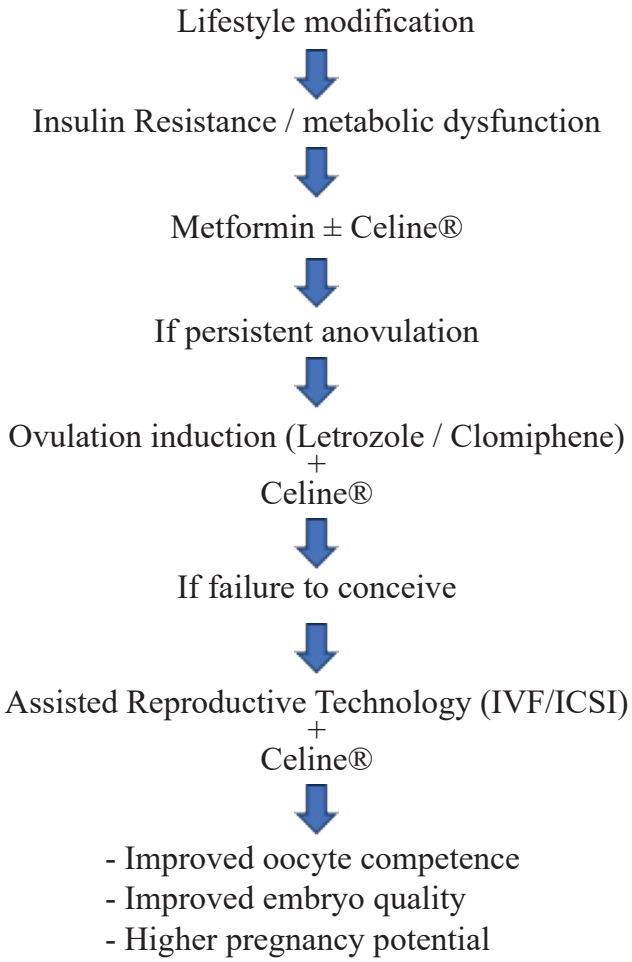


Figure 1. *Proposed clinical positioning of Celine® across the continuum of PMOS management.*
The available evidence suggests that Celine® may have a complementary role throughout the management pathway of PMOS, supporting metabolic correction, restoration of ovulation, and optimization of assisted reproductive technology outcomes. This continuum-of-care approach reflects the complementary findings of the three published clinical studies and provides a practical framework for the clinical integration of Celine®.

Conclusions

Across these three studies, Celine® supplementation is consistently associated with favorable reproductive and metabolic outcomes in women with PMOS, and this is broadly consistent with the mechanistic rationale for its components. At the same time, this remains a preliminary generated evidence base where data comes from three non-comparable study

designs, and includes one study with no control group at all.

Perhaps the most important observation emerging from the available evidence is that the three studies do not describe independent clinical indications but rather successive stages of the same therapeutic journey. The evidence suggests that Celine® may accompany women with PMOS from the correction of metabolic dysfunction, through restoration of ovulation, and ultimately to optimization of assisted reproductive outcomes when advanced fertility treatment becomes necessary. This continuum distinguishes Celine® from interventions that target only a single stage of disease management and supports its integration into a broader, multidisciplinary approach to PMOS care.

Hence, based on the currently available evidence, Celine® should not be viewed as an alternative to established therapies such as lifestyle intervention, metformin, ovulation-inducing agents, or assisted reproductive technology. Instead, it may be positioned as a complementary adjunctive therapy that addresses the metabolic and oxidative mechanisms underlying PMOS and may enhance the effectiveness of conventional treatments across different stages of patient management.

While the available findings are encouraging, further and larger (similar to study C), independently conducted, adequately powered randomized controlled trials with harmonized outcome measures are needed to confirm the optimal timing, duration, and target patient populations for Celine® supplementation, and to enable robust pooled analyses in future systematic reviews and meta-analyses

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