Polycystic Ovary Syndrome (PCOS) Protocol

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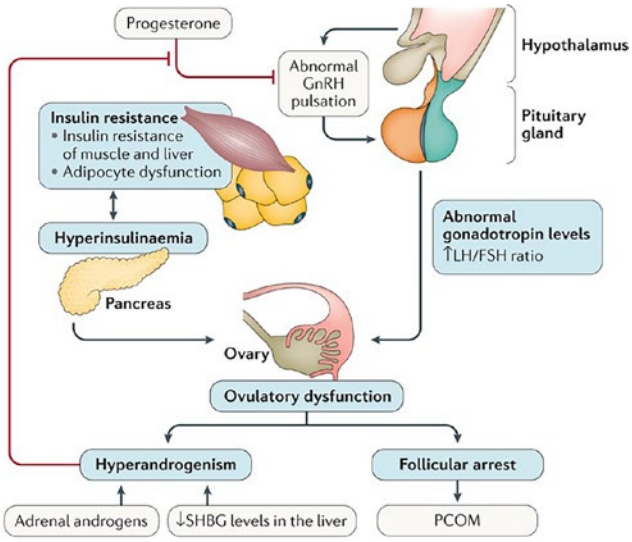
Clinical Protocol to Support Healthy Hormone Balance*



Azziz, R., Carmina, E., Chen, Z. et al. Polycystic ovary syndrome. Nat Rev Dis Primers 2, 16057 (2016). https://doi.org/10.1038/nrdp.2016.57

Polycystic Ovary Syndrome (PCOS) is a reproductive disorder with multiple comorbidities that can also affect metabolic processes. PCOS is often associated with insulin resistance and a higher risk of developing type 2 diabetes. Two of three symptoms diagnosed by health-care practitioners are indicative of this disorder: (1) lack of or irregular menstruation affecting ovulation; (2) higher androgen levels; and (3) multiple, small cysts in the ovaries.[1] PCOS affects between 6% and 12% of women in the U.S., which equates to about 5 million women with reduced chances of conception.[1] PCOS is the most common cause of infertility.[1]

Previous research has demonstrated an "association of the gut microbiome with metabolic markers and type 2 diabetes with PCOS."[3] Some patients are at risk of obesity, high blood pressure, cardiovascular disease, stroke, high low-density and low high-density cholesterol levels, and sleep apnea.[2] The intervention of lifestyle modification through a healthy diet and regular exercise has been shown to promote normal ovulation and fertility in patients with PCOS.[3]

This clinical protocol is designed to support healthy hormone balance and glucose metabolism through evidence-based dietary, lifestyle, and nutritional strategies for individuals with PCOS.*

Diagnostic Biomarkers and Clinical Indicators of PCOS[4-10]

- **Anti-Mullerian Hormone**
  - Normal: 1.0 ng/ml
  - High: > 3.0 ng/ml
- **Sex hormone-binding globulin (SHBG)**
  - Females (non-pregnant): 18-144 nmol/L
- **Testosterone**
  - Total:
    Ages 19 to 49: 8 - 48 ng/dL
    Ages 50 and older: 2 - 41 ng/dL
  - Free: 0.3 to 2 pg/mL
- **Hemoglobin A1C (HA1C)**
  - Normal: 4% to 5.6%
  - Prediabetes: 5.7% to 6.4%
  - Diabetes: ≥ 6.5%
- **Fasting Insulin**
  - Normal: < 5 uIU/mL
- **Homeostatic Model Assessment of Insulin Resistance (HOMA-IR)**
  - Normal: 0.7 and 2.0
  - Indicates IR: > 2.0
- **Total Cholesterol**
  - 125 to 200 mg/dL
- **Genomic Spotlight**
  - Endocrine Health
- **Metabolomics Spotlight**
  - Energy Metabolism and Hormones

Therapeutic Diet and Nutritional Considerations

- Recommend a low carbohydrate diet with a reduction in refined carbohydrates and high-glycemic foods and beverages.
- Recommend patients achieve the RDA of dietary fiber (28 g/day) intake through fiber-rich foods:
  - Non-starchy vegetables: rainbow chard, kale, bok choy, cauliflower, spinach, cabbage, asparagus, Brussels sprouts, broccoli, and broccoli sprouts
  - Low-glycemic fruits: berries, plums, apples, peaches, pears, pomegranates, and cherries
  - Legumes: lentils, chickpeas, black beans, navy beans
  - Nuts/seeds: flax, chia, hemp, walnuts
- Achieve minimum intake of chromium (25 mcg/day). Insulin resistant women with PCOS were found to have significantly lower serum chromium levels compared with controls.[12]
- Emphasize healthy proteins and fats for snacks and alongside carbohydrates during meals to help regulate blood sugar.

Lifestyle Interventions

- Recommend an appropriate exercise program, combining resistance training along with cardiovascular exercise to support healthy bodyweight and insulin function.
- Encourage walking 10,000 steps per day - brisk walking and aerobic exercise demonstrate benefit to hormonal parameters (androgen and SHBG levels) in patients with PCOS.[11]

Supplement Protocol

Primary Support:

Sensitol™

Dose	2 capsules twice per day on an empty stomach
Duration	Ongoing as needed
Formula Highlights	Sensitol™ is a unique formulation comprised of two naturally occurring isomers of inositol—myo-inositol (MI) and D-chiroinositol (DCI)—along with alpha lipoic acid, designed to support normal insulin function and cellular metabolism.* Inositol occurs naturally as nine isomers in a variety of vegetable and animal foods as well as in the human body. The MI and DCI isomers have been recognized to be the most predominant and have important functions in human physiology, such as mediating normal cell signaling from insulin and from sex and thyroid hormones.*

Metabolic Synergy™

Dose	2 capsules 2 to 3 times per day
Duration	Ongoing as needed
Formula Highlights	Metabolic Synergy™ helps maintain healthy glucose and insulin metabolism, while supporting the conversion of carbohydrates to be used for energy by providing nutrients for the Krebs cycle.* The chromium, zinc, selenium, manganese, and molybdenum are provided as true chelates for maximum absorption and bioavailability. This formula also contains targeted levels of R-lipoic acid, taurine insert and carnosine to support healthy glucose metabolism.*

OmegAvail™ Synergy

Dose	2 softgels per day
Duration	Ongoing as needed
Formula Highlights	OmegAvail™ Synergy has a unique blend of omega 3-6-7-9 fatty acids. It contains 270 mg of eicosapentaenoic acid (EPA) and 180 mg of docosahexaenoic acid (DHA) in the TruTG™ form, along with gamma-linoleic acid (GLA) from borage oil, palmitoleic acid, and oleic acid from certified-virgin organic macadamia nut oil and borage oil.

For a list of references cited in this document, please visit:
https://www.designsforhealth.com/api/library-assets/literature-reference---polycystic-ovary-syndrome-references

Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health-care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations regarding herb-drug and nutrient-drug interactions, please refer to reliable, evidence-based resources such as the Natural Medicine Database or Stargrove MB, Treasure J, McKee DLHer. *Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategies*. St. Louis, MO: Mosby-Elsevier; 2008.

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**