

**Full Title** Phase 2, Multicenter, Double-blind (Sponsor-unblinded), Randomized, Placebo-Controlled Study of the Safety and Efficacy of Elagolix in Women with Polycystic Ovary Syndrome

**Principal Investigator** Stephen Fehnel, MD

**Study Objectives** The objective of the study is to assess the pharmacokinetics, pharmacodynamics, safety, and efficacy of elagolix in women with PCOS.

**Sub-Investigators** Xuezhi Jiang, MD  
Mark Martens, MD

**Inclusion Criteria** Patients are eligible if they are Women 18 to 35 years of age with PCOS and a BMI 18.5 to 35 kg/m<sup>2</sup>, inclusive.

**Exclusion Criteria** Excluded patients will include:

- Pregnant or breastfeeding or planning a pregnancy until completion of the study
- Patients with active PID at screening
- Women less than 6 months post-partum, post-abortion, post-pregnancy, and post-lactation at the time of entry into the Screening Period
- Women with osteoporosis or other metabolic bone disease
- Women diagnosed with Cushing's syndrome, late onset congenital adrenal hyperplasia, androgen-secreting tumors, uncontrolled thyroid disease, hyperprolactinemia, diabetes mellitus, HIV, or major depression or PTSD episode within 2 years prior to screening

**Affiliations & Sponsors** AbbVie

**Status** Open to Enrollment

**Keywords** Polycystic Ovary Syndrome, PCOS, elagolix, chronic oligoanovulation, androgen excess, hormonal disorders