PCOS Research Study

Inclusion Criteria:

Patients interested in study participation should meet the following criteria:

- Diagnosis of PCOS as defined by the Rotterdam criteria
- Females age 21-40 years old
- BMI 25-40 kg/m^2
- Willingness to comply with study protocol for 6 months + 3 month follow-up
- Not actively planning pregnancy during study duration (10 months)
- Willingness to give written informed consent to participate in the study

Exclusion criteria can be found on the Patient Screening Questionnaire.

Proposed Study Summary:

Study will last for six months of active study time with three months of observational follow-up. Three groups will be involved in the study. Groups 1 & 2 will be comprised of women interested in receiving lifestyle counseling during the study. Group 3 will be an observational group and will not have lifestyle counseling during the study.

- **Groups 1 and 2** are comprised of women who <u>are</u> interested in receiving dietary and lifestyle counseling throughout the course of the study. Both groups will receive the same recommendations throughout the course of the study and will be asked to take study products as directed, wear an activity monitor, and complete menstrual calendars. Participants wills receive all study products ($210 - $2030 value), activity monitor ($120 value), and all study tests (ultrasounds, office visits, laboratory work) required for the study at no charge.
- **Group 3** is comprised of women who are <u>not</u> interested in lifestyle modifications at this time but who would like to assist in increasing knowledge of PCOS and its effects on the body. Group 3 participants will be observational only during the course of the research study. Group 3 will receive all study tests (ultrasounds, office visits, laboratory work) required for the study at no charge and will be eligible for up to 4 visits of nutrition counseling at the end of the study if desired ($340 value). These visits must be used by the participant and must be used within 4 months of the end of study participation. Group 3 participants will also be eligible for one free Clomid monitoring cycle through ReproMed Fertility at the completion of their study participation ($600-$800 value).

Study participants can expect to spend approximately 10 months in the study including screening and enrollment visits. Study participation will be comprised of 14 office visits and 1 phone consultation for Groups 1 and 2 and 13 office visits for Group 3 participants.

Individuals interested in study participation may ask their physician for more information or may contact our office directly.

Healthy Living Dallas

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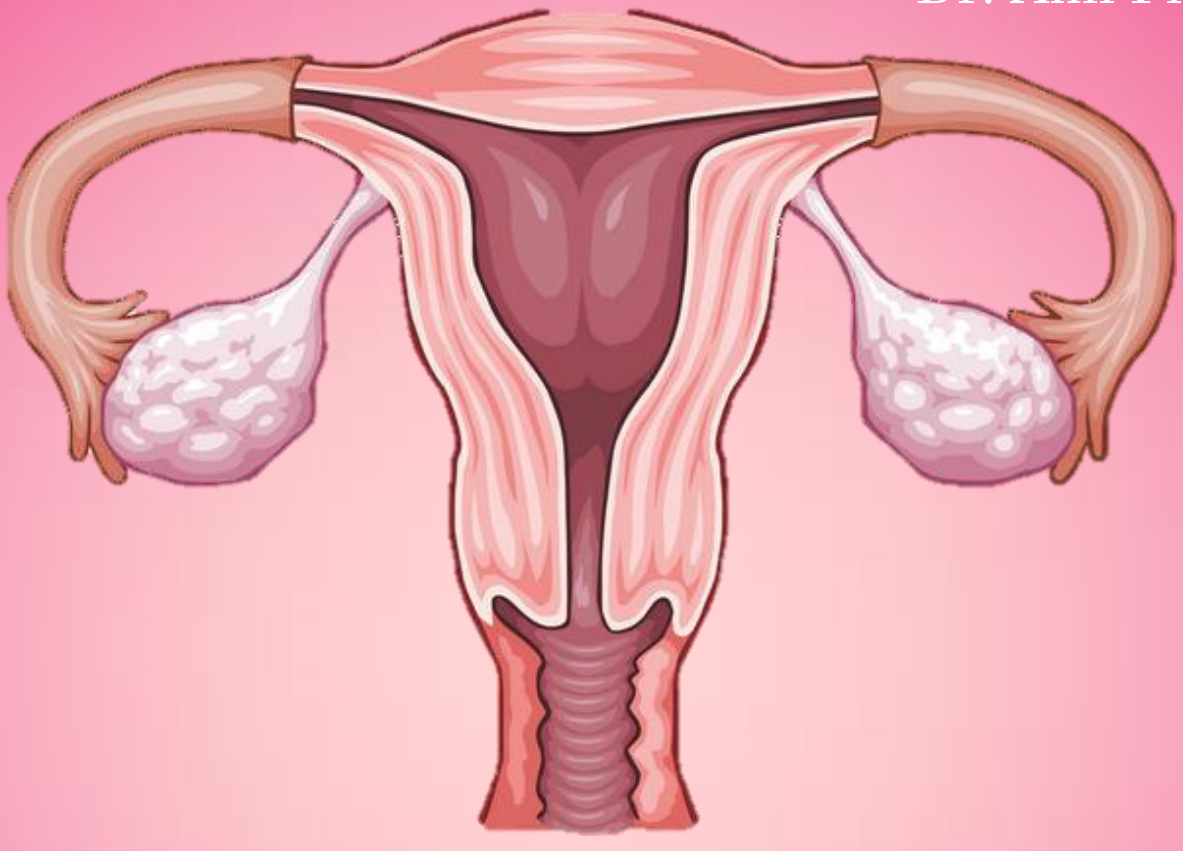
Polycystic Ovary Syndrome
Research Study

Dr. Anil Pinto



A voluntary research study is currently being conducted to evaluate the use of lifestyle modifications on polycystic ovary syndrome (PCOS) progression and symptoms.

PCOS is a disorder of the endocrine system that is common in women of childbearing age. This change in hormone release can demonstrate as infrequent or prolonged menstrual periods, excess body hair growth, acne, and obesity.

This study is currently enrolling participants who are interested in helping advance the research for PCOS and potential lifestyle-based treatments. The study will have three groups of participants: those who do not want to make lifestyle changes at this time as well as two groups who are interested in receiving dietary and lifestyle counseling as a part of the study.

Study participants will receive blood work and ultrasounds at regular intervals during study participation (six months + 3 month follow-up). All patients will receive all necessary study supplies free of charge.